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A cluster randomized controlled trial to determine the effect of community mobilization and advocacy on men's use of violence in peri-urban South Africa: Study protocol

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ABSTRACT

Objective: This paper describes the design and methods of a cluster randomised controlled trial to determine the effectiveness of a community mobilization intervention that is designed to reduce the perpetration of violence against women (VAW).

Methods and analysis: A cluster randomized controlled trial (C-RCT) of 18 clusters is being carried out in a peri-urban, semi-formal settlement, north of Johannesburg, South Africa between 2016 and 2018. A community mobilization intervention called Sonke CHANGE is being implemented over 18 months. It comprises advocacy and group activities to engage community members to challenge harmful gender norms and reduce VAW. The intervention is hypothesized to improve equitable masculinities, reduce alcohol use, and ultimately, to reduce VAW. Intervention effectiveness will be determined through an audio computer-assisted questionnaire with self-reported behavioural measures at baseline, 12 months and 24 months. The primary trial outcome is men's use of physical and / or sexual violence against women. Secondary outcomes include harmful alcohol use, gender attitudes and sexual behaviours. The main analysis will be intention-to-treat based on the randomization of clusters. A qualitative process evaluation is being conducted alongside the C-RCT. Implementers and men participating in the intervention will be interviewed longitudinally over the period of intervention implementation.

Ethics and dissemination: Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee. Informed consent procedures comply with ethical recommendations of the United Nations Multi-Country Study on Men and Violence. Dissemination of the research findings will take place at different stages and in different settings.

Discussion: The study will contribute to our understanding of what works to prevent violence against women. It will also provide insight into the contextual factors that can facilitate and impede intervention delivery. Donors and governments are committed to primary prevention of VAW and this trial can inform an evidenced-based approach to violence prevention.

Strengths and limitations of this study:

- The Sonke CHANGE trial will contribute to the limited body of evidence from low- and middle-income countries of what works to prevent violence against women and girls.
- Randomisation of clusters occurred after recruitment and baseline data collection
- Intention to treat analysis will be conducted.
- The risk of contamination in the C-RCT is high due to the close physical proximity of the clusters and the nature of the intervention (community mobilization)
- Loss to follow up is a potential study limitation

INTRODUCTION

Violence against women (VAW) is a leading cause of morbidity and mortality among the 35% of women globally who experience it [1 2]. Prevalence of VAW is high in Southern Africa. Large studies among South African men found that 27.5 – 31.8% report enacting violence towards partners [3], and 27.6% of men have ever raped [4]. These high rates of violence against partners and non-partners are consistent with population-based findings from studies among men in other regions globally [5 6].

There is a growing consensus that hegemonic masculinities lead to harmful health behaviors, including VAW [7]. Research suggests that men who strictly adhere to dominant norms of masculinity (e.g. toughness, virility, power) are more likely to perpetrate VAW [6 8] However, the evidence base for precisely *how* interventions can encourage men to reconstruct masculinities and whether this would result in a reduction of perpetration of VAW is limited. Much of the literature focuses on the problems of masculinity [9], and evidence from existing programs is restricted to a handful of small interventions [10 11]. In South Africa two trials with primary outcomes that aimed to reduce the incidence of HIV had some promising results at reducing VAW. The IMAGE trial combined economic intervention with gender training workshops and reported a reduction in women's past year VAW by 51% [12]. Stepping Stones, a series of community-based workshops with women and men, showed a 38% reduction on men's perpetration of violence after two years of follow up [10].

Sonke Gender Justice (Sonke), a South African nongovernmental organization, has been running gender transformative, community-based programs since 2006. Sonke CHANGE

intervention is delivered through a series of group workshops and other reflective activities to challenge harmful gender norms and educate men about gender-based violence and HIV risks [13 14]. The theory underpinning the intervention is that through community outreach and advocacy, harmful values and practices can be transformed toward gender equity and thereby reduce VAW. Equitable masculine norms manifest through behaviours and attitudes that are considered to reduce the likelihood of VAW (e.g. equality, respect, intimacy, responsibility) [15 16]. The Sonke CHANGE intervention posits that masculine norms can be progressively transformed through community activities that stimulate personal as well as collective reflection and action.

This type of gender transformative intervention is under-researched [17], but there is preliminary qualitative evidence though that such an approach is promising [18 19]. In order to reach global goals of eliminating VAW [20], it is crucial to understand how multilevel programming may impact men's use of violence. The aim of the cluster randomized controlled trial (C-RCT) is to determine the effectiveness of the Sonke CHANGE intervention to prevent men's use of VAW and reduce the severity of perpetration by men aged 18 to 40 years living in a peri-urban South African settlement over two years of follow-up.

METHODOLOGY

This trial is funded by the United Kingdom Agency for International Development through the What Works to Prevent Violence, a global consortium of research managed by the South African Medical Research Council. What Works had broad input on the scientific and ethical considerations of study design, and has an advisory role in data collection, management,

analysis, and interpretation of data. The writing and submission of the report is the decision of the investigative team.

The Consolidated Standards of Reporting Trials (CONSORT) and Standard Protocol Items for Randomized Trials (SPIRIT) guidelines have been followed, and the study protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials. The protocol is registered with ClinicalTrials.gov (NCT02823288) under the name: Multilevel Intervention for Preventing Men's Use of Violence in Urban South Africa (Sonke CHANGE Trial).

Participants, interventions and outcomes

The trial is being conducted in a semi-formal 'township" located near Johannesburg, South Africa. The peri-urban settlement took form in the mid-1990s, when the fall of apartheid 'pass laws' allowed non-whites to move closer to cities to seek employment. Most residents live in government-subsidised housing and informal tin shacks. Few exact population estimates exist, but most assume the 'township' is now home to between 250 000 and a half million people, including high numbers of migrants from other African countries. Many residents lack access to basic services such as running water, sewage and rubbish removal. Citizen officials estimate that half the population in the settlement is unemployed [21].

Recruitment of participants is led by the trial researchers among men who lived in the area for at least 12 months and were 18-40 years old. Men over the age of 40 years will not be prevented from participating in community mobilization or any of the Sonke CHANGE intervention activities but will not be eligible to be recruited for the trial. The study will be

described as a project about men's lives and relationships, rather than about violence, to prevent undue stigma for study participation [22].

Trial Design

A two-arm C-RCT will be conducted as shown in Figure 1. Due to the informality of geographic boundaries within the peri-urban settlement, a cluster is defined as a neighbourhood bordered by a community landmark such as a church, community hall or communal water source. These landmarks were mapped through transect walks using global positioning systems coordinates obtained on a Samsung S4 Tablet application *Map Coordinates*. The 18 clusters were evenly spaced throughout the community and contained dwellings falling within a radius of 0.4 kilometers of each community landmark.

Clusters identified for inclusion in the study are not contiguous and each is bordered by a natural boundary (such as a stream) or by a sizeable physical distance of at least 400 metres. While contamination is a concern, spillover effects in this type of C-RCT cannot be perfectly contained. Any intentional or unintentional contamination will be measured through a series of items on the questionnaire that determine participant exposure to specific intervention components. This data will be triangulated with qualitative process evaluation data to provide a contextualized understanding of contamination/spillover effects.

Insert Figure 1 about here

Intervention activities

The Sonke CHANGE Intervention is being implemented over a period of 18 months (April 2016 to November 2017). Sonke Gender Justice will conduct a range of using a multi-level

approach to stimulate critical reflection among men and promote equitable gender norms and non-violent masculine attitudes and practices. Intervention activities are comprised of workshops, mobilization led by Community Action Teams (CATs), and advocacy (see Table 1).

Table 1. CHANGE Intervention activities

Activity	*Frequency*	*Target per site, per activity*
1. CHANGE Workshops		
Recruit potential CAT members	Ongoing as needed	15
5 day training	Once off for CATs	15
Individual commitment to action & report-back (community bystander activities)	Monthly	5
Refresher training	Quarterly	12
2. CAT Community mobilisation		
Door-to-door campaign	2 x week	60
Street intervention (banner/poster discussion)	2 x week	10
CHANGE Workshops – 2 day training	2 x Month	30
Mini-workshops (1-2 hours) held in local taverns, churches, schools	Weekly	12
Digital stories film screenings	2 x Month	50
Mural paintings	2 x Month	80
Ambush theatre	Monthly	50
Community dialogues	Monthly	80
Debate session (at schools) – community mobiliser	Monthly	30
Most significant change story	Monthly (start at 6 months)	1
Stakeholder meeting (CBOs, Community police forums, community leaders)	2 x week	80
Street soccer – GBV information or debate	Quarterly	15
Open houses to discuss a topic or theme	Quarterly	60
Training CBOs (3 days)	Annually	30
3. Advocacy		
Lobbying	TBD	TBD
Marching/protest	TBD	TBD
Media advocacy	TBD	TBD

Workshops aim to challenge inequitable and harmful ideas about manhood and encourage men to take action to promote equality [23 24]. They draw on Freireian popular education pedagogy and principles and promote reflection and a commitment to action [25 26]. A

dedicated workshop curriculum has been developed specific to the goals of the Sonke CHANGE intervention.

Community Action Teams (CATs) are comprised of men and women who mobilise community members on a voluntary basis around issues of gender transformation. These CATs initiate a number of activities such as workshops, ambush theatre (spontaneous theatre that occurs on the street), door to door educational outreach, and community dialogues. CAT activities aim to reach a large number of people in each community to achieve "saturation" of new ideas and social norms.

Local advocacy is undertaken by CAT members, who aim to hold government and other duty bearers to account for VAW prevention. CAT members join local community structures such as community policing forums, school governing bodies, hospital committees, church groups, and football-clubs and use their presence to advance community education and local government accountability.

Workshops address hegemonic masculinities on the personal level; CATs address hegemonic masculinity norms at a community level; and local advocacy addresses hegemonic masculinity on the level of governance. Together this multilevel approach intends to stimulate critical reflection at the individual, social and political levels.

In the control cluster, communities receive the standard care. This choice of comparator is deemed ethical since little evidence exists for the efficacy and safety of the intervention being tested. Any pre-existing interventions or community-based activities will continue. However, communities in the control arm will not be intentionally exposed to Sonke CHANGE

intervention activities. One caveat is that local advocacy may necessarily overlap across cluster boundaries, since it is likely to engage large parts of the peri-urban community. This scientific limitation will be accounted for during follow-up data collection, which asks individuals about their exposure to Sonke advocacy.

Outcome Measures

The long-term goal of the intervention is to reduce men's use of intimate partner and non-partner violence against women. A number of primary and secondary measures have been defined *a priori.*

Primary Outcome Measure: Men's Reported Violence

Men's use of violence towards an intimate partner is measured using an adapted version of the questionnaire from the South African Medical Research Council's Study on Men's Health and Relationships [6 27]. The questionnaire includes items around emotional abuse, economic abuse, physical violence, and sexual violence. Primary outcomes will be defined as dichotomous outcomes: any use of physical violence and/or any use of sexual violence. Sensitivity analysis will be conducted around intensity of violence use, using the likert scale responses to violence items to create an index of violence intensity [28].

Secondary Outcome Measures

Harmful alcohol use is measured using the Alcohol Use Disorders Identification Test, a 10-item scale designed to measure alcohol consumption and identify risks for alcohol abuse and dependence [29].

Gender Attitudes are measured using the Gender Equitable Men's Scale [30] and the Gender Norms scale on whether a man perceives that his community holds those beliefs [31].

Male Controlling Behaviour is measured using the Pulerwitz Sexual Relationship Power and Control scale items [32]. This scale has been validated in South Africa [33], and has been used by members of our team in previous studies [34].

Parenting is measured by the Parent-Child Conflict Tactics Scale, a series of items about parental psychological abuse and physical discipline of children [35].

Transactional sex is measured using the Medical Research Council's standard measure for South Africa. This measures transactional sex among casual partners [31].

Social cohesion is assessed using a measure from the Stepping Stones questionnaire [36].

Participant views and participation in violence-related campaigns is assessed using items from the Gender Links survey [31].

Covariates

Partnership characteristics include basic demographics about sexual partners and sexual behaviour from the Stepping Stones questionnaire [36].

Socio-economic status is assessed using items from the United Nations Multi-country Study around education, marital status, household size, and monthly income.

Food security is measured using the Household Hunger Scale, a 3-item measure developed by the USAID-funded Food and Nutrition Technical Assistance (FANTA) project [37].

Drug use is measured using a single question from the United Nations Multi-country Study around past year use: "How many times have you used drugs in the last 12 months?"

Mental health is measured using multiple scales. Depression will be measured using the CES-D, a brief, validated instrument based on the nine diagnostic criteria for DSM-IV depressive disorders [38]. The Harvard Trauma Questionnaire (HTQ) is a cross-cultural instrument for measuring symptoms associated with post-traumatic stress disorder [39].

Power estimates

Little data is available to estimate incidence of men's use of VAW in South Africa. However, one population-based study that used a representative sample by Gender Links in Gauteng Province provides a point estimate of past-year use of violence among men. In this Gender Links study, 12% of men used physical or sexual violence towards a partner in the past 12 months [31]. Thus, based on 12% incidence, we can estimate the study's power to detect a 4% difference if VAW decreases to 8%. The power calculation is based on 150 participants per cluster in 18 clusters. A 20% adjustment for potential loss to follow up increases to 180 the total number of men to be recruited in each cluster with a total sample size of 2880. Figure 2 shows the power calculations for 6, 7 and 8 clusters per arm with a coefficient of variance ranging between 5% and 50%. Data will be collected at three time points: baseline, 12 month and 24 months.

[Insert Figure 2 about here]

Assignment of intervention

Randomisation of clusters into the intervention or control arm was undertaken after the baseline data collection was completed. See Figure 3 for the timing of allocation and assessments.

[Insert Figure 3 about here]

All cluster names were printed on equal sized pieces of paper and the randomisation will be performed at a public event. The event was held with local leadership, trial researchers and Sonke staff in a public setting to ensure randomisaton is transparent to the community. Each local leader chose one cluster name from a bag until nine clusters were allocated to the

intervention arm. Clusters cannot be blinded to their study arm allocation after the initial data collection, nor can intervention implementers be blinded to arm allocation.

Participant enrollment

Study enrollment was initiated through a series of community meetings held in each cluster and door-to-door recruitment of men by trial staff. Men in the 18 clusters were invited to take part in a written informed consent process and thereafter asked to complete a Locator Form by a trained field worker. The Locator Form is the primary method of participant retention, and has information about the participant's dwelling and phone numbers. Locator Form data is stored separately from any other participant data to ensure confidentiality.

Data collection, management and analysis

Data collection occurs in private, confidential locations such as a community hall, or yard identified in each cluster. Data collection is facilitated by trained interviewers, and conducted in the language of participant choice (English, isiZulu, and Sepedi). Interviewers will use an electronic data system called Open Data Kit on 7-inch Samsung tablet computers that operate on the Android platform. These tablet computers are inexpensive and easy-to-carry, and allow ease of data collection. Electronic data collection provides a standardized method that minimizes user bias and improves data quality as it precludes data entry of paper forms. Security of data can be improved through use of electronic data collection (versus using paper forms), since data is uploaded to an encrypted server at the end of each day. The server is housed at the university and has been purpose-built for this study.

We will use audio-computer assisted data collection (ACASI) since sensitive questions around violence can be sensitive and it is ethically challenging to handle disclosure [40]. Use of ACASI prevents complex ethical issues such as professional obligations to report criminal

activities (such as rape) and better ensures anonymity and confidentiality, which may lead to more accurate reporting of VAW.

Community Advisory Board

Prior to starting data collection, the team set up a community advisory board (CAB) comprising local leadership. The members include non-governmental organisations, local residents, and ward councilors (local political representatitves). Once sensitised to the trial and intervention, the CAB introduced the study, the intervention, the ethical considerations of participating, and the intended outcomes to people in the community. This serves as an opportunity to set expectations around reporting back findings to the community.

Data management and statistical analyses

Data from the baseline interviews and follow-up interview data will be abstracted from Open Data Kit databases built specifically for this study. Procedures to promote data quality will include range and logical checks built into Open Data Kit and running additional error checks after data abstraction.

The main analysis will be intention-to-treat based on the randomization of clusters. The prevalence and incidence of violence perpetration will be calculated. In addition, we will analyse trends in intensity of violence perpetration over the 24 months of follow up.

Since allocation to the intervention or control arms was by cluster, all statistical assessments of variability will use the cluster as the unit of analysis. Rate ratios of incidence of men's use of VAW in intervention/control groups will be calculated as geometric means of the cluster-pair ratios, with 95% confidence intervals (CIs) derived from *t* intervals of log-transformed

incidence rates with equal weighting per cluster. Adjusted rate ratios of incidence of VAW perpetration in the intervention group relative to the control group will be based on a Poisson multiple regression model of incidence rates, by comparison of observed to expected incidence in each cluster. Covariates in the model will include community prevalence of men's use of VAW at baseline, socio-demographic, partner and attitude variables found to differ between study groups at enrolment, and variables hypothesised as related to VAW. These variables will include age, socio-economic status, connectedness to the community, relationship status, numbers of reported sex partners in the past year, gender attitudes, experiences of childhood trauma, depression, post-traumatic stress disorder and sex for payment or gifts.

Additional analyses will focus on assessing the effects of the intervention on mediating factors such as harmful alcohol use, partner communication and collective efficacy. Analyses for mediating variables will either treat scores as continuous measures or categorise them according to clinical cut-offs. Initial comparisons will be based on group-specific descriptive summaries of observed outcomes and tests comparing outcomes between groups these could include ttests (for parametric) or Wilcoxon Mann-Whitney/Wilcoxon Signed Rank tests (for nonparametric) data and chi-squared for categorical data. We will also use multivariable models regression methods to compare outcomes between groups while controlling for baseline characteristics.

Analyses for outcomes will proceed similarly, with appropriate choices of model for outcome type. For example, we will use logistic regression models for between-group (baseline and follow up) comparisons of perpetration of violence over the previous 12 months. We will also make preliminary assessments of degree of mediation in models for primary outcomes via inclusion of mediating factors, with assessment of direct and indirect intervention effects of key mediating variables [41].

Process Evaluation

A process evaluation will employ a research design that is qualitative and longitudinal over the period of the trial implementation, 2016-2018. It is therefore designed to collect data that enables rich description and captures the subjective experiences of people involved in the Sonke CHANGE intervention at all levels as the intervention unfolds over time.

Data collection

A range of data collection techniques will be used for the process evaluation:

Semi-structured interviews will be used to collect data from a range of different actors connected to the Sonke CHANGE intervention, including stakeholders (Sonke managers [n = 5], investigators [n=3], and community leaders [n=5]); intervention implementers (mobilisers [n=5], CAT members [n=5], and fieldworkers [n=5]); and research participants [n=10]. In total, 38 participants will be interviewed using a semi-structured topic guide. Participants will be asked questions regarding the intervention implementation, contextual factors that may shape primary and secondary outcomes, and experiences in the intervention.

Maximum variation sampling will be used in order to ensure a wide range of perspectives are represented among stakeholders, implementers and participants [42]. This will enable the collection of data that provides insights from different perspectives and enable analysis of common themes and divergent opinions across groups of actors.

Over the course of the Sonke CHANGE intervention each of the 38 interviewees will be interviewed on multiple occasions: stakeholders twice and implementers and participants on three occasions. In total 101 interviews will be conducted. The collection of longitudinal

interview data will enable analysis of shifts in perspectives and insights into how transformation might occur through participation in the intervention.

Participant-observation will be conducted in order to collect data from the intervention activities that take place. Participant-observation data will be collected in a semi-structured manner by a dedicated process evaluation researcher. This researcher will purposively attend at least one of each type of intervention activity. Participant-observation will ensure unanticipated developments in the Sonke CHANGE intervention are captured (e.g. an unplanned intervention activity). Participant-observation data will provide insight into the contextual factors that impede and facilitate the implementation of the Sonke CHANGE trial.

Data analysis

Analysis of process evaluation data will be iterative and will be managed using qualitative software. Content analysis will be used to describe the processes of participant behavior change over time in order to determine what kinds of changes occur in men participating in intervention activities. A secondary focus will be placed on analysing theoretical themes that are identified across, and between, the qualitative data set in order to explore how and why identified changes in perceptions, beliefs or behaviour occur. A final focus will be placed on interpreting findings in order to explain the nature and meaning of changes in perception, belief or behaviour as well as to further theory development and determine the transferability of the study's findings to other contexts.

Ethics and dissemination

Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee. Changes to the protocol are submitted to this body, and the funder is made aware of relevant amendment approvals after they are obtained.

Researchers received intensive training on VAW, the study protocol, collecting sensitive information, and ensuring data quality and participant confidentiality. Informed consent procedures comply with ethical recommendations of the University of Witwatersrand and of the United Nations Multi-Country Study on Men and Violence [40]. Prospective participants will be informed that they do not have to participate in the trial unless they are happy with the trial procedures and understand what the trial is about. All participants will be told that participation is voluntary, that they may withdraw at any stage, skip any question in the research and that there are no adverse effects should they decide not to participate. For the success of the project we require all research participants to agree in principle to multiple interviews (i.e. baseline, 12months and 24 months) - although they may change their mind.

The participant information leaflets and consent forms are written in simple English, however to enhance understanding, the explanation and discussion may be in isiZulu, Sepedi, Tsonga, or English depending on the participant's language preference. A researcher will be present throughout the informed consent process and will clarify any questions the participants are not clear about. Once they are fully informed about the study, they will be asked to sign informed consent for the interview. Participants also will be asked for written informed consent to have their interview digitally recorded. Anonymity is important because of the sensitive nature of some of the questions. All questionnaires will be identified by study identification numbers that are directly assigned by the electronic data system.

Adverse Reporting

In social and behavioral trials, it is important for researchers to 'go beyond' typical medical reporting (which includes only physical health outcomes like hospitalization or mortality) and report on social harms. We will take the most conservative approach to reporting and include all potential social harms within our definition of adverse events, as noted in italics. **Adverse Events** (AEs) are any untoward medical *or social* occurrence that may present during intervention but which does not necessarily have a causal relationship with this *project.* AEs include risks to participant or fieldworker safety and any breach of confidentiality. **Serious Adverse Events** are any untoward medical *or social* occurrence that results in death or significant disability or *incapacity (including incarceration).* SAEs may also include civil unrest or natural disaster in a study site that has the potential to put at serious risk the interviewers, participants or data quality. All reporting will follow protocol established by the University of Witwatersrand Ethics Committee.

Data Monitoring

A data monitoring committee was not established for this trial since the intervention is implemented at the community level, limiting the ability of an outside body to determine a statistical or ethical rationale for stopping rules. The Community Advisory Board does serve as a local accountability mechanism for data at baseline and endline.

Dissemination

The final trial dataset will be made accessible to trial investigators for a period of five years. During this time, scholarly dissemination will take place through peer-reviewed journals and community dissemination will occur through a series of workshops with key community

stakeholders and members of the network of nongovernmental organisations working in the area to address VAW and children.. After five years, the trial dataset will be made available to other researchers through an online portal managed by the What Works program.

DISCUSSION

There are many well-documented efforts to reduce violence against women from industrialised countries in North America and Europe [43 44], with limited evidence from low and middle-income country settings. Many of the evaluated interventions have focused on the response to VAW rather than on primary prevention. Interventions that address the response to VAW have shown impact on physical and mental health outcomes for women but there is limited evidence that these interventions reduce violence.

There are limitations inherent to the design of the C-RCT. The risk of contamination is high due to the close physical proximity of the clusters and the nature of the intervention, which includes community mobilization and advocacy elements. In addition, our formative research has revealed that men's movement within the 'township' is fairly common, which means that over the two years of follow up men may move from an intervention to a control cluster or vice versa. Our analysis will be based on intention to treat to address the movement of men across clusters. We recruited participants and then randomized the clusters after baseline data collection. However, once the intervention activities commence it will no longer be possible to blind participants or implementers to which arm of the cluster they have been randomized. As with all longitudinal studies, loss to follow up is a potential study limitation. Efforts will be made to collect different types of contact information of participants as well as up to four close friends or family members.

The Sonke CHANGE trial will contribute to the limited body of evidence from low- and middle-income countries of what works to prevent violence against women and girls. It will contribute to a growing set of studies that have explored whether gender transformative approaches work to reduce VAW. The trial together with the process evaluation will provide insight on whether the hypothesized pathways to change are relevant and appropriate. Moreover, we will gain insight into how change happens, if at all. Identifying and measuring interventions for addressing men's use of violence against women is essential if we are to ensure the health and wellbeing of women, children, and men themselves.

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Competing interests: None of the authors have any competing interests

Author contributions

NC: conceptualized the study together with AH and AP, wrote the first draft of the manuscript

AH: conceptualized the project together with NC and AP; made substantial contributions to the writing of the manuscript

RM: refined the process evaluation and contributed to the description of the process evaluation in the manuscript

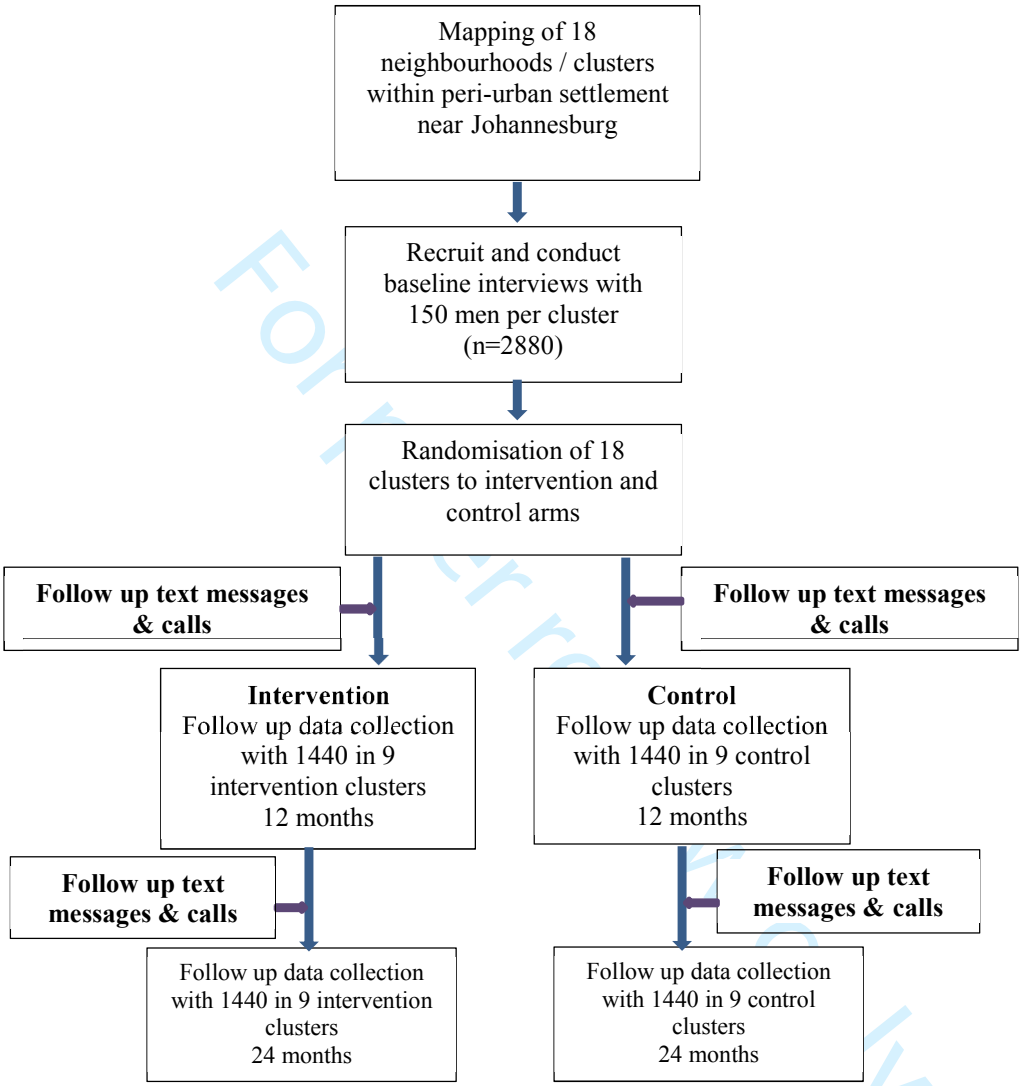
DP, DR, AP and AA: developed and refined the Sonke intervention which the C-RCT is evaluating and commented on the manuscript

1. WHO. Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence. Geneva: World Health Organization, 2013.
2. Devries KM, Mak JY, Garcia-Moreno C, et al. The global prevalence of intimate partner violence against women. Science 2013;**340**(6140):1527-8 doi: 10.1126/science.1240937
science.1240937 [pii][published Online First: Epub Date]|.
3. Dunkle KL, Jewkes RK, Nduna M, et al. Perpetration of partner violence and HIV risk behaviour among young men in the rural Eastern Cape, South Africa. AIDS 2006;**20**(16):2107-14
4. Jewkes R, Sikweyiya Y, Morrell R, et al. Gender inequitable masculinity and sexual entitlement in rape perpetration South Africa: findings of a cross-sectional study. PLoS One 2011;**6**(12):e29590 doi: 10.1371/journal.pone.0029590
PONE-D-11-14447 [pii][published Online First: Epub Date]|.
5. Barker G, Contreras JM, Heilman B, et al. Evolving Men: Initial Results from the International Men and Gender Equality Survey (IMAGES. Washington,D.C.: International Centerfor Research on Women (ICRW) and Instituto Promundo, 2011.
6. Fulu E, Warner X, Miedema S, et al. Why do some men use violence against women and how can we prevent it? Findings from the UN Multi-country study on men and violene in Asia and the Pacific. Bangkok: UNDP, UNFPA, UN Women, UNV, 2013.
7. Jewkes R, Morrell R. Gender and sexuality: emerging perspectives from the heterosexual epidemic in South Africa and implications for HIV risk and prevention. J Int AIDS Soc 2010;**13**:6 doi: 1758-2652-13-6 [pii]
10.1186/1758-2652-13-6[published Online First: Epub Date]|.
8. Santana MC, Raj A, Decker MR, et al. Masculine gender roles associated with increased sexual risk and intimate partner violence perpetration among young adult men. J Urban Health 2006;**83**(4):575-85 doi: 10.1007/s11524-006-9061-6[published Online First: Epub Date]|.
9. Mankowski ES, Maton KI. A community psychology of men and masculinity: historical and conceptual review. Am J Community Psychol 2010;**45**(1-2):73-86 doi: 10.1007/s10464-009-9288-y[published Online First: Epub Date]|.
10. Jewkes R, Nduna M, Levin J, et al. Impact of stepping stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial.[see comment]. BMJ 2008;**337**:a506
11. Kalichman SC, Simbayi LC, Cloete A, et al. Integrated gender-based violence and HIV Risk reduction intervention for South African men: results of a quasi-experimental field trial. Prevention Science 2009;**10**(3):260-69
12. Pronyk PM, Hargreaves JR, Kim JC, et al. Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial. Lancet 2006;**368**(9551):1973-83
13. Van den Berg W, Hendricks L, Hatcher A, et al. 'One Man Can': shifts in fatherhood beliefs and parenting practices following a gender-transformative programme in Eastern Cape, South Africa. Gender & Development 2013;**21**(1):111-25
14. Peacock RD, Reneke PA, Forney GP. *CFAST-consolidated model of fire growth and smoke transport (version 6) user's guide*: Citeseer, 2013.
15. Connell RW. *Gender and power: Society, the person and sexual politics*: John Wiley & Sons, 2014.

16. Shefer T. *From boys to men: Social constructions of masculinity in contemporary society*: Juta and Company Ltd, 2007.
17. What Works to Prevent Violence. Summary of the Evidence and Research Agenda for What Works: A Global Programme to Prevent Violence against Women and Girls. London: UKAid, 2014.
18. Dworkin SL, Hatcher AM, Colvin C, et al. Impact of a gender-transformative HIV and antiviolence program on gender ideologies and masculinities in two rural, South African communities. Men and masculinities 2013;**16**(2):181-202
19. Hatcher AM, Colvin CJ, Ndlovu N, et al. Intimate partner violence among rural South African men: alcohol use, sexual decision-making, and partner communication. Cult Health Sex 2014;**16**(9):1023-39 doi: 10.1080/13691058.2014.924558[published Online First: Epub Date]|.
20. Garcia-Moreno C, Amin A. The sustainable development goals, violence and women's and children's health. Bull World Health Organ 2016;**94**(5):396-7 doi: 10.2471/BLT.16.172205[published Online First: Epub Date]|.
21. Mahajan S. Economic of South African townships: special focus on Diepsloot. A World Bank study. Washington DC: World Bank Group, 2014.
22. Jewkes R, Dartnall E, Sikweyiya Y. Ethical and Safety Recommendations for Research on the Perpetration of Sexual Violence. Pretoria, South Africa: Sexual Violence Research Initiative, Medical Research Council, 2012.
23. Courtenay WH. Constructions of masculinity and their influence on men's well-being: a theory of gender and health. Soc Sci Med 2000;**50**(10):1385-401 doi: S0277953699003901 [pii][published Online First: Epub Date]|.
24. Messner MA. *Politics of masculinities: Men in movements*: Sage Publications, Inc, 1997.
25. Freire P. *Pedagogy of the Oppressed*. New York: Continuum, 1970.
26. Freire P. *Education for Critical Consciousness*. New York: Continuum, 1973.
27. Jewkes R, Sikweyiya Y, Morrell R, et al. The relationship between intimate partner violence, rape and HIV amongst South African men: a cross-sectional study. PLoS One 2011;**6**(9):e24256 doi: 10.1371/journal.pone.0024256
PONE-D-11-04522 [pii][published Online First: Epub Date]|.
28. Tsai AC, Tomlinson M, Comulada WS, et al. Intimate Partner Violence and Depression Symptom Severity among South African Women during Pregnancy and Postpartum: Population-Based Prospective Cohort Study. PLoS Med 2016;**13**(1):e1001943 doi: 10.1371/journal.pmed.1001943[published Online First: Epub Date]|.
29. Saunders JB, Aasland OG, Babor TF, et al. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO Collaborative Project on Early Detection of Persons with Harmful Alcohol Consumption--II. Addiction 1993;**88**(6):791-804
30. Pulerwitz J, Barker G. Measuring attitudes towards gender norms among young men in Brazil: Development and psychometric evaluation of the GEM scale. Men and Masculinities 2008;**10**:322-38
31. MRC. War at Home: Preliminary findings of the Gauteng Gender Violence Prevalence Study Johannesburg,: Gender Links and the Medical Research Council, 2010.
32. Pulerwitz J, Amaro H, De Jong W, et al. Relationship power, condom use and HIV risk among women in the USA. AIDS Care 2002;**14**(6):789-800
33. Dunkle KL, Jewkes RK, Brown HC, et al. Gender-based violence, relationship power, and risk of HIV infection in women attending antenatal clinics in South Africa. Lancet 2004;**363**(9419):1415-21 doi: 10.1016/S0140-6736(04)16098-4
S0140-6736(04)16098-4 [pii][published Online First: Epub Date]|.
34. Hatcher AM, Tsai AC, Kumbakumba E, et al. Sexual Relationship Power and Depression among HIV-Infected Women in Rural Uganda. PloS one 2012;**7**(12):e49821

35. Straus MA, Hamby SL, Finkelhor D, et al. Identification of child maltreatment with the Parent-Child Conflict Tactics Scales: Development and psychometric data for a national sample of American parents. Child abuse & neglect 1998;**22**(4):249-70
36. Jewkes R, Nduna M, Levin J, et al. Impact of stepping stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial. Bmj 2008;**337**:a506
37. Deitchler M, Ballard T, Swindale A, et al. Validation of a measure of household hunger for cross-cultural use. Washington, DC: Food and Nurtrition Technical Assistance II Project (FANTA-2), Acedemy for Educational Development 2010
38. Radloff LS. The CES-D scale A self-report depression scale for research in the general population. Applied psychological measurement 1977;**1**(3):385-401
39. Mollica RF, Caspi-Yavin Y, Bollini P, et al. The Harvard Trauma Questionnaire. Validating a cross-cultural instrument for measuring torture, trauma, and posttraumatic stress disorder in Indochinese refugees. J Nerv Ment Dis 1992;**180**(2):111-6
40. Fulu E, Jewkes R. Replicating the UN Multi-Country Study on men and violence: Understanding why some men use violence against women and how we can prevent it. Bangkok, Thailand: Partners for Prevention, 2014.
41. Petersen ML, Sinisi SE, van der Laan MJ. Estimation of direct causal effects. Epidemiology 2006;**17**(3):276-84 doi: 10.1097/01.ede.0000208475.99429.2d 00001648-200605000-00012 [pii][published Online First: Epub Date]|.
42. Patton MQ. *Qualitative research*: Wiley Online Library, 2005.
43. Wathen CN, MacMillan HL. Interventions for violence against women: scientific review. Jama 2003;**289**(5):589-600
44. Ramsay J, Rivas C, Feder G. *Interventions to reduce violence and promote the physical and psychosocial well-being of women who experience partner violence: A systematic review of controlled evaluations: Final report*: Barts and the London, Queen Mary's School of Medicine and Dentistry, 2005.

Figure 1: Flow diagram showing the trial recruitment and proposed follow up at 12 and 24 months



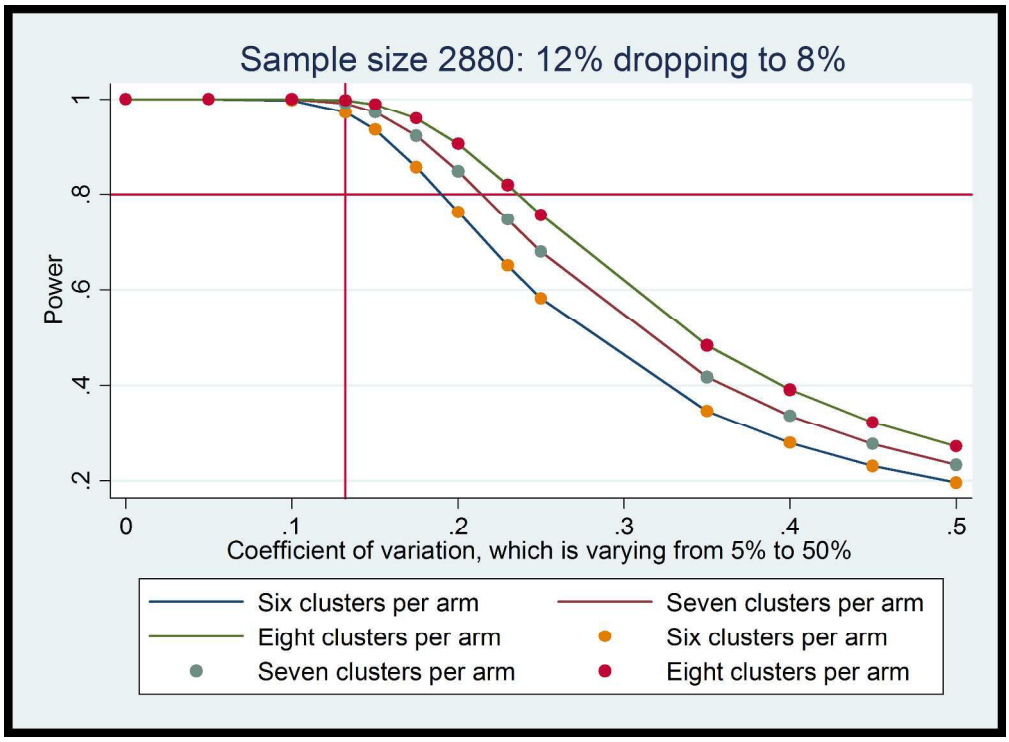


Figure 2: Power calculation

890x651mm (96 x 96 DPI)

Figure 3. Schedule of enrolment, interventions, and assessments for the Sonke CHANGE trial

	STUDY PERIOD: January 2016-July 2018						
	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT	***Feb-April 2016***	***April 2016***	***May-Dec 2016***	***Feb-Jul 2017***	***Aug-Dec 2017***	***Jan-Jun 2018***	***July 2018***
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
[Sonke Intervention]			—	—	—		
[Control/standard care]			—	—	—		
ASSESSMENTS:							
[Date of birth, education, housing, food security, income, childhood trauma questionnaire]	X						
[Use of sexual and/or physical violence]	X			X		X	
[Alcohol use, gender attitudes, male controlling behavior, parenting, social cohesion]	X			X		X	
[Partnership characteristics, drug use, depression, PTSD]	X			X		X	

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	____1_____
	2b	All items from the World Health Organization Trial Registration Data Set	____1-13_____
Protocol version	3	Date and version identifier	_____1_____
Funding	4	Sources and types of financial, material, and other support	_____1_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	____1_____
	5b	Name and contact information for the trial sponsor	____1_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	____6_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	____n/a_____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	4-5
	6b	Explanation for choice of comparators	10
Objectives	7	Specific objectives or hypotheses	6
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	7-8
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	6
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	6
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	9-11
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	n/a
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	n/a
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	n/a
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	11-13
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	9. Fig 3

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	____13_____
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_____7_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	____14_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	___14_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	____14_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	____14_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	____n/a_____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	____15_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	____14-15_____

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16-17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	22
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	21-22
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	20

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	20
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	25
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	23
	31b	Authorship eligibility guidelines and any intended use of professional writers	25
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	23
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary materials
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

A cluster randomized controlled trial to determine the effect of community mobilization and advocacy on men's use of violence in peri-urban South Africa: Study protocol

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Complete List of Authors:	Christofides, Nicola; University of Witwatersrand, School of Public Health Hatcher, Abigail; University of Witwatersrand, School of Public Health; University of California San Fransisco Division of Human Immunodeficiency Virus/Acquired Immune Deficiency Syndrome Pino, Angelica; Sonke Gender Justice Rebombo, Dumisani; Sonke Gender Justice McBride, Ruari; University of Witwatersrand, School of Public Health Anderson, Althea; Sonke Gender Justice Peacock, Dean; Sonke Gender Justice
Primary Subject Heading:	Global health
Secondary Subject Heading:	Research methods, Public health, Evidence based practice
Keywords:	Cluster randomized controlled trial, behavioural intervention, perpetration of violence against women, working with men and boys, gender-based violence, South Africa

TITLE: A cluster randomized controlled trial to determine the effect of community mobilization and advocacy on men's use of violence in peri-urban South Africa: Study protocol

Registration: ClinicalTrials.gov Identifier: NCT02823288, registered on June 30 2016

Registered title: Multilevel Intervention for Preventing Men's Use of Violence in Urban South Africa (Sonke CHANGE Trial)

Funded by: What Works to Prevent Violence against Women and Girls programme, South African Medical Research Council, and UKAID; contact person: Prof Rachel Jewkes, rachel.jewkes@mrc.ac.za

Protocol version 1.2: June 15, 2016

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Word count: 5175

Key words: Cluster randomized controlled trial, behavioural intervention, perpetration of violence against women, working with men and boys, gender-based violence, South Africa

ABSTRACT

Objective: This paper describes the design and methods of a cluster randomized controlled trial to determine the effectiveness of a community mobilization intervention that is designed to reduce the perpetration of violence against women (VAW).

Methods and analysis: A cluster randomized controlled trial (C-RCT) of 9 intervention and 9 control clusters is being carried out in a peri-urban, semi-formal settlement near Johannesburg, South Africa between 2016 and 2018. A community mobilization intervention called Sonke CHANGE is being implemented over 18 months. It comprises advocacy and group activities to engage community members to challenge harmful gender norms and reduce VAW. The intervention is hypothesized to improve equitable masculinities, reduce alcohol use, and ultimately, to reduce VAW. Intervention effectiveness will be determined through an audio computer-assisted questionnaire with self-reported behavioral measures among 2600 men aged between 18 and 40 years at baseline, 12 months and 24 months. The primary trial outcome is men's use of physical and / or sexual violence against women. Secondary outcomes include harmful alcohol use, gender attitudes, controlling behaviors, transactional sex and social cohesion. The main analysis will be intention-to-treat based on the randomization of clusters. A qualitative process evaluation is being conducted alongside the C-RCT. Implementers and men participating in the intervention will be interviewed longitudinally over the period of intervention implementation and observations of the workshops and other intervention activities are being carried out.

Ethics and dissemination: Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee and procedures comply with ethical

recommendations of the United Nations Multi-Country Study on Men and Violence. Dissemination of research findings will take place with local stakeholders and through peer-reviewed publications, with data available upon request or after 5 years of trial completion.

Strengths and limitations of this study:

- There is limited evidence from low- and middle-income countries of what works to prevent men's use violence against women and girls
- A cluster randomized trial testing community mobilization and advocacy may a prove promising way to reduce men's violence use
- Strengths include randomization of clusters after baseline data collection and intention to treat analysis.
- Limitations include risk of contamination across clusters and potential loss-to follow-up of men over 2 years

INTRODUCTION

Violence against women (VAW), including sexual and/or physical violence, is a leading cause of morbidity and mortality among the 35% of women globally who experience it. [1, 2] Prevalence of intimate partner and non-partner violence against women is high in Southern Africa. Large studies among South African men found that 27.5 – 31.8% report enacting physical and / or sexual violence towards partners, [3] and 27.6% of men have ever raped.[4] These high rates of violence against partners and non-partners are consistent with population-based findings from studies among men in other regions globally.[5, 6]

There is a growing consensus that hegemonic masculinities lead to harmful health behaviors, including VAW.[7] Research suggests that men who strictly adhere to dominant norms of masculinity (e.g. toughness, virility, power) are more likely to perpetrate VAW.[6, 8] However, the evidence base for precisely *how* interventions can encourage men to reconstruct masculinities and whether this would result in a reduction of perpetration of VAW is limited. Much of the literature focuses on the problems of masculinity,[9] and evidence from existing programs is restricted to a handful of small interventions.[10, 11] In South Africa two trials with primary outcomes that aimed to reduce the incidence of HIV had some promising results at reducing VAW. The IMAGE trial combined economic intervention with gender training workshops and reported a reduction in women's reports of past year VAW by 51%.[12] Stepping Stones, a series of community-based workshops with women and men, showed a 38% reduction in men's perpetration of violence after two years of follow up.[10]

Sonke Gender Justice (Sonke), a South African nongovernmental organization, has been running gender transformative, community-based programs since 2006. The core Sonke intervention has evolved over more than 10 years and is premised on mobilizing communities to take action against VAW. The activities include a series of group workshops and other reflective activities to challenge harmful gender norms and educate men about gender-based violence and HIV risks.[13, 14] The theory underpinning the intervention is that through community outreach and advocacy, harmful values and practices can be transformed toward gender equity and thereby reduce VAW. Equitable masculine norms manifest through behaviors and attitudes that are considered to reduce the likelihood of VAW (e.g. equality, respect, intimacy, responsibility).[15, 16] The Sonke CHANGE intervention adds to existing Sonke activities by bolstering community action and local advocacy specifically around men's use of VAW. CHANGE stands for "Community Health Action for Norms and Gender Equity" and posits that masculine norms can be progressively transformed through community activities that stimulate personal as well as collective reflection and action.

This type of gender transformative intervention is under-researched,[17] but there is preliminary qualitative evidence though that such an approach is promising.[18, 19] In order to reach global goals of eliminating VAW,[20] it is crucial to understand how multilevel programming may impact men's use of violence. The aim of the cluster randomized controlled trial (C-RCT) is to determine the effectiveness of the Sonke CHANGE intervention to prevent men's use of VAW and reduce the severity of perpetration by men aged 18 to 40 years living in a peri-urban South African settlement over two years of follow-up.

METHODOLOGY

This trial is funded by the United Kingdom Agency for International Development through What Works to Prevent Violence, a global consortium of research managed by the South African Medical Research Council. What Works had broad input on the scientific and ethical considerations of study design, and has an advisory role in data collection, management, analysis, and interpretation of data. The writing and submission of the report is the decision of the investigative team.

The Consolidated Standards of Reporting Trials (CONSORT) and Standard Protocol Items for Randomized Trials (SPIRIT) guidelines have been followed, and the study protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials. The protocol is registered with ClinicalTrials.gov (NCT02823288) under the name: Multilevel Intervention for Preventing Men's Use of Violence in Urban South Africa (Sonke CHANGE Trial).

Participants, interventions and outcomes

The trial is being conducted in a semi-formal 'township" located near Johannesburg, South Africa. The peri-urban settlement took form in the mid-1990s, when the fall of apartheid 'pass laws' allowed non-whites to move closer to cities to seek employment. Most residents live in government-subsidized housing and informal tin shacks. Few exact population estimates exist, but most assume the 'township' is now home to between 250 000 and a half million people, including high numbers of migrants from other African countries. Many residents lack access to basic services such as running water, sewerage and rubbish removal. Citizen officials estimate that half the population in the settlement is unemployed.[21]

Recruitment of participants was led by the trial team of trained research assistants. Men who lived in the area for at least 12 months and were 18-40 years old were eligible to be recruited. Men over the age of 40 years are not being prevented from participating in community mobilization or any of the Sonke CHANGE intervention activities but were not be eligible to be recruited for the trial. The study is described as a project about men's lives and relationships, rather than about violence, to prevent undue stigma for study participation.[22]

Trial Design

A two-arm C-RCT is being conducted as shown in Figure 1. Due to the informality of geographic boundaries within the peri-urban settlement, a cluster is defined as a neighborhood bordered by a community landmark such as a church, community hall or communal water source. These landmarks were mapped through transect walks using global positioning systems coordinates obtained on a Samsung Tablet application *Map Coordinates*. The 18 clusters, identified for the purposes of the trial, were evenly spaced throughout the community and contained dwellings falling within a radius of 0.4 kilometers of each community landmark.

Clusters identified for inclusion in the study are not contiguous and each is bordered by a natural boundary (such as a stream) or by a sizeable physical distance of at least 400 metres. While contamination is a concern, spillover effects in this type of C-RCT cannot be perfectly contained. Any intentional or unintentional contamination is being measured through a series of items on the questionnaire that determine participant exposure to specific intervention components. This data will be triangulated with qualitative process evaluation data to provide a contextualized understanding of contamination/spillover effects.

Insert Figure 1 about here

Intervention activities

The Sonke CHANGE Intervention is being implemented over a period of 18 months (April 2016 to November 2017). Sonke Gender Justice is implementing a multi-level approach to stimulate critical reflection among men and promote equitable gender norms and non-violent masculine attitudes and practices. The Sonke core intervention staff comprises a full-time manager and six community mobilisers (3=men, 3=women) recruited from the community where the study is taking place. Two community mobilisers are responsible for three intervention clusters. Intervention activities are comprised of workshops initially run by community mobilisers, mobilization led by Community Action Teams (CATs), and advocacy (see Table 1). Community mobilizers received extensive training over several months, comprised of a manualized curriculum that includes participatory activities, values clarification, and shadowing established mobilisers working in a different community.

Table 1. CHANGE Intervention activities

Activity	*Frequency*	*Target people reached per cluster, per activity*
1. CHANGE Training		
Recruit potential CAT members	Ongoing as needed	15
5 day training	Once off for Community Action Team (CAT) members	15
Individual commitment to action & report-back (community bystander activities)	Monthly	5
Refresher training	Quarterly	12
2. CAT Community mobilization		
Door-to-door campaign	2 x week	60
Street intervention (banner/poster discussion)	2 x week	10
CHANGE Workshops – 2 day training	2 x Month	30
Mini-workshops (1-2 hours) held in local taverns, churches, schools	Weekly	12
Digital stories film screenings	2 x Month	50
Mural paintings	2 x Month	80

Ambush theatre	Monthly	50
Community dialogues	Monthly	80
Debate session (at schools) – community mobiliser	Monthly	30
Most significant change story	Monthly (start at 6 months)	1
Stakeholder meeting (CBOs, Community police forums, community leaders)	2 x week	80
Street soccer – VAW information or debate	Quarterly	15
Open houses to discuss a topic or theme	Quarterly	60
Training local organizations (3 days)	Annually	30
3. Advocacy		
Lobbying	Ongoing	TBD
Marching/protest	Ongoing	TBD
Media advocacy	Ongoing	TBD

Workshops aim to challenge inequitable and harmful ideas about manhood and encourage men to take action to promote equality.[23, 24] They draw on Freirean education pedagogy and principles and promote reflection and a commitment to action.[25, 26] A dedicated workshop curriculum was developed specific to the goals of the Sonke CHANGE intervention, with additional materials created to bolster emphasis on VAW prevention.

Community Action Teams (CATs) are comprised of men and women who mobilize community members on a voluntary basis around issues of gender transformation. CATs are recruited through workshops that are run by community mobilizers. Participants who are particularly interested in the content of the workshops are invited to join a CAT. In practice, CAT members include approximately 20-40 members of the local community, all of whom live in intervention clusters. The process of recruiting and training CAT members occurs on an ongoing basis, depending on retention and planned mobilization activities. CATs are trained through week-long, manualized workshops that are led by Sonke Community Mobilizers. Following training and a process of shadowing the Community Mobilizers (lasting between 1 and 6 months, depending on the skills of the CAT members), CATs initiate a number of activities throughout all 9 intervention clusters, such as workshops,

ambush theatre (spontaneous theatre that occurs on the street), door-to-door educational outreach, and community dialogues. CAT activities aim to reach a large number of people in each community to achieve "saturation" of new ideas and social norms. CATs receive transportation reimbursement but do not receive a salary for their efforts.

Advocacy is undertaken by Sonke staff including community mobilizers, who aim to hold government and other duty bearers to account for VAW prevention. Sonke staff join local community structures such as community policing forums, school governing bodies, hospital committees, church groups, and football-clubs and use their presence to advance community education and local government accountability.

Workshops address hegemonic masculinities on the personal level; CATs address hegemonic masculinity norms at a community level; and advocacy addresses hegemonic masculinity on the level of governance. Together this multilevel approach intends to stimulate critical reflection at the individual, social and political levels.

In the control cluster, communities receive the standard care. This choice of comparator is deemed ethical since little evidence exists for the efficacy and safety of the intervention being tested. Any pre-existing interventions or community-based activities are continuing. However, communities in the control arm are not being intentionally exposed to Sonke CHANGE intervention activities. One caveat is that advocacy may necessarily overlap across cluster boundaries, since it is likely to engage large parts of the peri-urban community. This scientific limitation will be accounted for during follow-up data collection, which asks individuals about their exposure to Sonke advocacy.

Outcome Measures

The long-term goal of the intervention is to reduce men's use of intimate partner and non-partner violence against women. A number of primary and secondary measures have been defined *a priori*.

Primary Outcome Measure: Men's Reported Violence

Men's use of violence towards an intimate partner is measured using an adapted version of the questionnaire from the South African Medical Research Council's Study on Men's Health and Relationships.[6, 27] The questionnaire includes items around emotional abuse, economic abuse, physical violence, and sexual violence. Primary outcomes will be defined as dichotomous outcomes: any use of physical violence and/or any use of sexual violence in the past 12 months. Sensitivity analysis will be conducted around intensity of violence use, using the Likert scale responses to violence items to create an index of violence intensity.[28]

Secondary Outcome Measures

Harmful alcohol use is measured using the Alcohol Use Disorders Identification Test, a 10-item scale designed to measure alcohol consumption and identify risks for alcohol abuse and dependence.[29]

Gender Attitudes are measured using the Gender Equitable Men's Scale[30] and the Gender Norms scale on whether a man perceives that his community holds those beliefs.[31]

Male Controlling Behaviour is measured using the Sexual Relationship Power and Control scale items.[32] This scale has been validated in South Africa,[33] and has been used by members of our team in previous studies.[34]

Parenting is measured by the Parent-Child Conflict Tactics Scale, a series of items about parental psychological abuse and physical discipline of children.[35]

Transactional sex is measured using the Medical Research Council's standard measure for South Africa. This measures transactional sex among casual partners.[31]

Social cohesion is assessed using a measure from the Stepping Stones questionnaire.[36] Participant views and participation in violence-related campaigns is assessed using items from the Gender Links survey.[31]

Covariates

Partnership characteristics include basic demographics about sexual partners and sexual behaviour from the Stepping Stones questionnaire.[36]

Socio-economic status is assessed using items from the United Nations Multi-country Study around education, marital status, household size, and monthly income.

Food security is measured using the Household Hunger Scale, a 3-item measure developed by the USAID-funded Food and Nutrition Technical Assistance (FANTA) project.[37]

Drug use is measured using a single question from the United Nations Multi-country Study around past year use: "How many times have you used drugs in the last 12 months?"

Mental health is measured using multiple scales. Depression is measured using the CES-D, a brief, validated instrument based on the nine diagnostic criteria for DSM-IV depressive disorders [38]. The Harvard Trauma Questionnaire (HTQ) is a cross-cultural instrument for measuring symptoms associated with post-traumatic stress disorder.[39]

Exposure to the intervention prior to baseline and in both intervention and control communities are being measured through a series of questions that ask about awareness of Sonke Gender Justice, participation in workshops and other activities.

Power estimates

Little data is available to estimate incidence of men's use of VAW in South Africa. However, one population-based study that used a representative sample by Gender Links in Gauteng Province provides a point estimate of past-year use of violence among men. In the Gender Links study, 12% of men used physical or sexual violence towards a partner in the past 12 months.[31] Thus, based on 12% past year prevalence, we can estimate the study's power to detect a 5% difference if VAW decreases to 7%. The power calculation is based on 150 participants per cluster in 18 clusters. A 20% adjustment for potential loss to follow up increases to 180 the total number of men to be recruited in each cluster with a total sample size of 2880. Figure 2 shows the power calculations based on Moulton and Hayes (2009) for 6, 7, 8 and 9 clusters per arm with a coefficient of variation (k) ranging between 5% and 50%.[40] Data will be collected at three time points: baseline, 12 month and 24 months.

[Insert Figure 2 about here]

Assignment of intervention

Randomisation of clusters into the intervention or control arm was undertaken after the baseline data collection was completed. See Figure 3 for the timing of allocation and assessments.

[Insert Figure 3 about here]

All cluster names were printed on equal sized pieces of paper and the randomisation was performed at a public event. The event was held with local leadership, trial researchers and Sonke staff in a public setting to ensure randomization is transparent to the community. Each local leader chose one cluster name from a bag until nine clusters were allocated to the

intervention arm. Clusters cannot be blinded to their study arm allocation after the initial data collection, nor can intervention implementers be blinded to arm allocation.

Participant enrollment

Study enrollment was initiated through a series of community meetings held in each cluster and door-to-door recruitment of men by trial staff. Men in the 18 clusters were invited to take part in a written informed consent process and thereafter asked to complete a Locator Form by a trained field worker. The Locator Form is the primary method of participant retention, and has information about the participant's dwelling and phone numbers. Locator Form data is stored separately from any other participant data to ensure confidentiality.

Data collection, management and analysis

Data collection occurs in private, confidential locations such as a community hall, or yard identified in each cluster. Data collection is facilitated by trained interviewers, and conducted in the language of participant choice (English, isiZulu, Tsonga, or Sepedi). Interviewers are using an electronic data system called Open Data Kit on 7-inch Samsung tablet computers that operate on the Android platform. These tablet computers are inexpensive and easy-to-carry, and allow ease of data collection. Electronic data collection provides a standardized method that minimizes user bias and improves data quality as it precludes data entry of paper forms. Security of data can be improved through use of electronic data collection (versus using paper forms), since data is uploaded to an encrypted server at the end of each day. The server is housed at the university and has been purpose-built for this study.

We are using audio-computer assisted data collection (ACASI) since sensitive questions around violence can be sensitive and it is ethically challenging to handle disclosure.[41] Use of ACASI prevents complex ethical issues because no interviewer or researcher can examine

responses to illegal questions until the data is de-identified. This inability to see individual data is important for questions around rape and physical or sexual mistreatment of children, since South African law requires mandatory reporting of these types of criminal activities. ACASI allows important data to be collected about legal and illegal activity while ensuring anonymity and confidentiality. Of note, the additional anonymity of ACASI may also lead to more accurate reporting of VAW by men since there would be no social desirability bias typically associated with interviewer-administered questionnaires.

Community Advisory Board

Prior to starting data collection, the team set up a community advisory board (CAB) comprising local leadership. The members include non-governmental organizations, local residents, and ward councilors (local political representatives). Once sensitized to the trial and intervention, the CAB introduced the study, the intervention, the ethical considerations of participating, and the intended outcomes to people in the community. This serves as an opportunity to set expectations around reporting back findings to the community.

Data management and statistical analyses

Data from the baseline interviews and follow-up interview data will be abstracted from Open Data Kit databases built specifically for this study. Procedures to promote data quality include range and logical checks built into Open Data Kit and running additional error checks after data abstraction.

The main analysis will be intention-to-treat based on the randomization of clusters. The period prevalence of violence perpetration over 24 months of follow-up will be calculated. The period prevalence of men's use of physical and/or sexual VAW over the previous 12

months among the intervention and control clusters will be compared as the primary trial outcome.

Since allocation to the intervention or control arms was by cluster, all statistical assessments of variability will use the cluster as the unit of analysis. Adjusted proportions of men reporting VAW perpetration in the intervention group relative to the control group will be compared, by comparison of observed to expected incidence in each cluster. Covariates in the model will include community prevalence (calculated using cluster means) of men's use of VAW at baseline, socio-demographic characteristics, relationship characteristics, mental health measures, and attitudinal variables.

Analyses for other primary and secondary outcomes will proceed similarly, with appropriate choices of model for outcome type. For example, we will use polytomous regression models to analyze intensity of men's VAW use at the different time points and by study condition. We will also make preliminary assessments of degree of mediation in models for primary outcomes via inclusion of mediating factors, with assessment of direct and indirect intervention effects of key mediating variables. [42]

Additional analyses will focus on assessing the effects of the intervention on mediating factors such as harmful alcohol use, partner communication and collective efficacy as indicated in the intervention Theory of Change (see Figure 4). Analyses for mediating variables will either treat scores as continuous measures or categorise them according to clinical cut-offs. Initial comparisons will be based on group-specific descriptive summaries of observed outcomes and tests comparing outcomes between groups (ttests for parametric or Wilcoxon Mann-Whitney/Wilcoxon Signed Rank tests for nonparametric data; chi-squared

for categorical data). We will also use multivariable models regression methods to compare outcomes between groups while controlling for baseline characteristics. ***[Insert Figure 4 about here]***

Process Evaluation

A process evaluation employs a research design that is qualitative and longitudinal over the period of the trial implementation, 2016-2018. It is designed to collect data that enables rich description and captures the subjective experiences of people involved in the Sonke CHANGE intervention as the intervention unfolds over time.

Data collection

A range of data collection techniques is being used for the process evaluation. In-depth interviews are conducted with stakeholders (Sonke managers [n = 5], trial investigators [n=3], and community leaders [n=5]); implementers (mobilisers [n=5], CAT members [n=5], and fieldworkers [n=5]); and research participants [n=10]. In total, 38 participants are being interviewed using a semi-structured topic guide. Participants are asked questions regarding the intervention implementation, contextual factors that may shape primary and secondary outcomes, and experiences in the intervention.

Maximum variation sampling is used in order to ensure a wide range of perspectives are represented among stakeholders, implementers and participants.[43] This enables the collection of data that provides insights from different perspectives and enables analysis of common themes and divergent opinions across groups of actors.

Over the course of the Sonke CHANGE intervention each of the 38 interviewees are being interviewed on multiple occasions: stakeholders twice and implementers and participants on

three occasions. In total 101 interviews will be conducted. The collection of longitudinal interview data will enable analysis of shifts in perspectives and insights into how transformation might occur through participation in the intervention.

Participant-observation is collected in a semi-structured manner by a process evaluation researcher with expertise in ethnographic methods. The researcher is purposively attending at least one of each type of intervention activity. Participant-observation will ensure unanticipated developments in the intervention are captured (e.g. an unplanned intervention activity). Participant-observation data will provide insight into the contextual factors that impede and facilitate the implementation of the Sonke CHANGE trial.

Data analysis

Analysis of process evaluation data will be iterative and will be managed using qualitative software. Content analysis will be used to describe the processes of participant behavior change over time in order to determine what kinds of changes occur in men participating in intervention activities. A secondary focus will be placed on analyzing theoretical themes that are identified across, and between, the qualitative data set in order to explore how and why identified changes in perceptions, beliefs or behavior occur. A final focus will be placed on interpreting findings in order to explain the nature and meaning of changes in perception, belief or behaviour as well as to further theory development and determine the transferability of the study's findings to other contexts.

Ethics and dissemination

Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee. Changes to the protocol are submitted to this body, and the funder is made aware of relevant amendment approvals after they are obtained.

Researchers received intensive training on VAW, the study protocol, collecting sensitive information, and ensuring data quality and participant confidentiality. Informed consent procedures comply with ethical recommendations of the University of Witwatersrand and of the United Nations Multi-Country Study on Men and Violence.[41] Prospective participants were informed that they do not have to participate in the trial unless they are happy with the trial procedures and understand what the trial is about. All participants were told that participation is voluntary, that they may withdraw at any stage, skip any question in the research and that there are no adverse effects should they decide not to participate. For the success of the project we require all research participants to agree in principle to multiple interviews (i.e. baseline, 12 months and 24 months) - although they may change their mind.

The participant information leaflets and consent forms are written in simple English, however to enhance understanding, the explanation and discussion may be in isiZulu, Sepedi, Tsonga, or English depending on the participant's language preference. A researcher was present throughout the informed consent process and clarified any questions the participants were not clear about. Once they are fully informed about the study, they were asked to sign informed consent for the interview. Participants also are asked for written informed consent to have their interview digitally recorded. Anonymity is important because of the sensitive nature of some of the questions. All questionnaires are identified by study identification numbers that are directly assigned by the electronic data system. Participants are reimbursed for their time

to participate in the study. An amount of R50 (approximately US $3.50) was paid to participants at the baseline data collection.

Participants who report sexual violence perpetrated against either partners or non-partners are not asked the age of the woman. South African law requires mandatory reporting of violence perpetrated against a minor (under the age of 18 years). Participants were informed during the consent process that if they disclose that they have perpetrated violence against a woman to the research assistant that the incident may need to be reported to the police. However, since research assistants do not actively ask any of the questionnaire items, the opportunities for participants to disclose illegal behaviors are reduced.

Should the intervention or research teams become aware of any women who have experienced partner or non-partner violence, a protocol is in place to refer women to local organizations that provide counseling and support for survivors. Should any men disclose personal experiences of violence or be supporting family members who have experienced violence similar referrals for counseling and support are made. The list of referral organizations was developed in consultation with members of the Community Advisory Board to ensure that services are accessible by community members and actively able to take new clients.

Adverse Reporting

In social and behavioral trials, it is important for researchers to 'go beyond' typical medical reporting (which includes only physical health outcomes like hospitalization or mortality) and report on social harms. We will take the most conservative approach to reporting and include

all potential social harms within our definition of adverse events, as noted in italics. **Adverse Events** (AEs) are any untoward medical *or social* occurrence that may present during intervention but which does not necessarily have a causal relationship with this *project.* AEs include risks to participant or fieldworker safety and any breach of confidentiality. **Serious Adverse Events** are any untoward medical *or social* occurrence that results in death or significant disability or *incapacity (including incarceration).* SAEs may also include civil unrest or natural disaster in a study site that has the potential to put at serious risk the interviewers, participants or data quality. All reporting is following protocol established by the University of Witwatersrand Ethics Committee.

Data Monitoring

A data monitoring committee was not established for this trial since the intervention is implemented at the community level, limiting the ability of an outside body to determine a statistical or ethical rationale for stopping rules. The Community Advisory Board does serve as a local accountability mechanism for data at baseline and endline. The scientific steering committee of What Works to Prevent Violence has access to all study protocols and conducts annual checks of data quality and scientific progress. However, unlike some cluster randomized trials, there is not a dedicated data monitoring committee, which may be viewed as a weakness of this study design.

Dissemination

The final trial dataset will be made accessible to trial investigators for a period of five years. During this time, scholarly dissemination will take place through peer-reviewed journals and community dissemination will occur through a series of workshops with key community

stakeholders and members of the network of nongovernmental organizations working in the area to address VAW and children. After five years, the trial dataset will be made available to other researchers through an online portal managed by the What Works to Prevent Violence program.

DISCUSSION

There are many well-documented efforts to reduce violence against women from industrialised countries in North America and Europe [44, 45], with limited evidence from low and middle-income country settings. Many of the evaluated interventions have focused on the response to VAW rather than on primary prevention. Interventions that address the response to VAW have shown impact on physical and mental health outcomes for women but there is limited evidence that these interventions reduce violence.

There are limitations inherent to the design of the C-RCT. Primary and secondary outcomes are self-reported which could result in either over- or under-reporting. It is unlikely that the self-reporting bias will be different in intervention and control clusters. One strength of the study is that we are collecting longitudinal qualitative data through the process evaluation which will allow for triangulation between different components of the study. However, we are not collecting data from female partners of male participants, due to the safety risks associated with such dyadic data collection. Therefore, like many studies in the violence field, the primary trial outcome will be based on self-reported measures.

The risk of contamination is high due to the close physical proximity of the clusters and the nature of the intervention, which includes community mobilization and advocacy elements.

In addition, our formative research has revealed that men's movement within the 'township' is fairly common, which means that over the two years of follow up men may move from an intervention to a control cluster or vice versa. Our analysis will be based on intention to treat to address the movement of men across clusters. We recruited participants and then randomized the clusters after baseline data collection. However, once the intervention activities commence it will no longer be possible to blind participants or implementers to which arm of the cluster they have been randomized. As with all longitudinal studies, loss to follow up is a potential study limitation. Efforts will be made to collect different types of contact information of participants as well as up to four close friends or family members. The two years of follow up data collection may be too short to measure an effect of the intervention since the recent use of violence is asked for the past 12 months. However, we believe that if the intervention is delivered as planned that changes in the primary outcome are possible.

The Sonke CHANGE trial will contribute to the limited body of evidence from low- and middle-income countries of what works to prevent violence against women and girls. It will contribute to a growing set of studies that have explored whether gender transformative approaches work to reduce VAW. The trial together with the process evaluation will provide insight on whether the hypothesized pathways to change are relevant and appropriate. Moreover, we will gain insight into how change happens, if at all. Identifying and measuring interventions for addressing men's use of violence against women is essential if we are to ensure the health and wellbeing of women, children, and men themselves.

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Competing interests: None of the authors have any competing interests

Author contributions

NC: conceptualized the study together with AH and AP, wrote the first draft of the manuscript

AH: conceptualized the project together with NC and AP; made substantial contributions to the writing of the manuscript

RM: refined the process evaluation and contributed to the description of the process evaluation in the manuscript

DP, DR, AP and AA: developed and refined the Sonke intervention which the C-RCT is evaluating and commented on the manuscript

Data sharing

Data will be made available via the funder UKAID once the final results of the study are published.

1. WHO. Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence. Geneva: World Health Organization, 2013.
2. Devries KM, Mak JY, Garcia-Moreno C, et al. The global prevalence of intimate partner violence against women. *Science* 2013; **340**(6140): 1527-8.
3. Dunkle KL, Jewkes RK, Nduna M, et al. Perpetration of partner violence and HIV risk behaviour among young men in the rural Eastern Cape, South Africa. *AIDS* 2006; **20**(16): 2107-14.
4. Jewkes R, Sikweyiya Y, Morrell R, Dunkle K. Gender inequitable masculinity and sexual entitlement in rape perpetration South Africa: findings of a cross-sectional study. *PLoS One* 2011; **6**(12): e29590.
5. Barker G, Contreras JM, Heilman B, Singh AK, Verma RK, Nascimento M. Evolving Men: Initial Results from the International Men and Gender Equality Survey (IMAGES. Washington,D.C.: International Centerfor Research on Women (ICRW) and Instituto Promundo, 2011.
6. Fulu E, Warner X, Miedema S, Jewkes R, Roselli T, Lang J. Why do some men use violence against women and how can we prevent it? Findings from the UN Multi-country study on men and violene in Asia and the Pacific. Bangkok: UNDP, UNFPA, UN Women, UNV, 2013.
7. Jewkes R, Morrell R. Gender and sexuality: emerging perspectives from the heterosexual epidemic in South Africa and implications for HIV risk and prevention. *J Int AIDS Soc* 2010; **13**: 6.
8. Santana MC, Raj A, Decker MR, La Marche A, Silverman JG. Masculine gender roles associated with increased sexual risk and intimate partner violence perpetration among young adult men. *J Urban Health* 2006; **83**(4): 575-85.
9. Mankowski ES, Maton KI. A community psychology of men and masculinity: historical and conceptual review. *Am J Community Psychol* 2010; **45**(1-2): 73-86.
10. Jewkes R, Nduna M, Levin J, et al. Impact of stepping stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial.[see comment]. *BMJ* 2008; **337**: a506.
11. Kalichman SC, Simbayi LC, Cloete A, et al. Integrated gender-based violence and HIV Risk reduction intervention for South African men: results of a quasi-experimental field trial. *Prevention Science* 2009; **10**(3): 260-9.
12. Pronyk PM, Hargreaves JR, Kim JC, et al. Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial. *Lancet* 2006; **368**(9551): 1973-83.
13. Van den Berg W, Hendricks L, Hatcher A, Peacock D, Godana P, Dworkin S. 'One Man Can': shifts in fatherhood beliefs and parenting practices following a gender-transformative programme in Eastern Cape, South Africa. *Gender & Development* 2013; **21**(1): 111-25.
14. Peacock RD, Reneke PA, Forney GP. CFAST-consolidated model of fire growth and smoke transport (version 6) user's guide: Citeseer; 2013.
15. Connell RW. Gender and power: Society, the person and sexual politics: John Wiley & Sons; 2014.
16. Shefer T. From boys to men: Social constructions of masculinity in contemporary society: Juta and Company Ltd; 2007.

17. What Works to Prevent Violence. Summary of the Evidence and Research Agenda for What Works: A Global Programme to Prevent Violence against Women and Girls. London: UKAid, 2014.
18. Dworkin SL, Hatcher AM, Colvin C, Peacock D. Impact of a gender-transformative HIV and antiviolence program on gender ideologies and masculinities in two rural, South African communities. *Men and masculinities* 2013; **16**(2): 181-202.
19. Hatcher AM, Colvin CJ, Ndlovu N, Dworkin SL. Intimate partner violence among rural South African men: alcohol use, sexual decision-making, and partner communication. *Cult Health Sex* 2014; **16**(9): 1023-39.
20. Garcia-Moreno C, Amin A. The sustainable development goals, violence and women's and children's health. *Bull World Health Organ* 2016; **94**(5): 396-7.
21. Mahajan S. Economic of South African townships: special focus on Diepsloot. Washington DC: World Bank Group, 2014.
22. Jewkes R, Dartnall E, Sikweyiya Y. Ethical and Safety Recommendations for Research on the Perpetration of Sexual Violence. Pretoria, South Africa: Sexual Violence Research Initiative, Medical Research Council; 2012.
23. Courtenay WH. Constructions of masculinity and their influence on men's well-being: a theory of gender and health. *Soc Sci Med* 2000; **50**(10): 1385-401.
24. Messner MA. Politics of masculinities: Men in movements: Sage Publications, Inc; 1997.
25. Freire P. Pedagogy of the Oppressed. New York: Continuum; 1970.
26. Freire P. Education for Critical Consciousness. New York: Continuum; 1973.
27. Jewkes R, Sikweyiya Y, Morrell R, Dunkle K. The relationship between intimate partner violence, rape and HIV amongst South African men: a cross-sectional study. *PLoS One* 2011; **6**(9): e24256.
28. Tsai AC, Tomlinson M, Comulada WS, Rotheram-Borus MJ. Intimate Partner Violence and Depression Symptom Severity among South African Women during Pregnancy and Postpartum: Population-Based Prospective Cohort Study. *PLoS Med* 2016; **13**(1): e1001943.
29. Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO Collaborative Project on Early Detection of Persons with Harmful Alcohol Consumption--II. *Addiction* 1993; **88**(6): 791-804.
30. Pulerwitz J, Barker G. Measuring attitudes towards gender norms among young men in Brazil: Development and psychometric evaluation of the GEM scale. *Men and Masculinities* 2008; **10**: 322-38.
31. MRC. War at Home: Preliminary findings of the Gauteng Gender Violence Prevalence Study Johannesburg,: Gender Links and the Medical Research Council, 2010.
32. Pulerwitz J, Amaro H, De Jong W, Gortmaker SL, Rudd R. Relationship power, condom use and HIV risk among women in the USA. *AIDS Care* 2002; **14**(6): 789-800.
33. Dunkle KL, Jewkes RK, Brown HC, Gray GE, McIntryre JA, Harlow SD. Gender-based violence, relationship power, and risk of HIV infection in women attending antenatal clinics in South Africa. *Lancet* 2004; **363**(9419): 1415-21.
34. Hatcher AM, Tsai AC, Kumbakumba E, et al. Sexual Relationship Power and Depression among HIV-Infected Women in Rural Uganda. *PloS one* 2012; **7**(12): e49821.
35. Straus MA, Hamby SL, Finkelhor D, Moore DW, Runyan D. Identification of child maltreatment with the Parent-Child Conflict Tactics Scales: Development and psychometric data for a national sample of American parents. *Child abuse & neglect* 1998; **22**(4): 249-70.

36. Jewkes R, Nduna M, Levin J, et al. Impact of stepping stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial. *Bmj* 2008; **337**: a506.
37. Deitchler M, Ballard T, Swindale A, Coates J. Validation of a measure of household hunger for cross-cultural use. *Washington, DC: Food and Nurtrition Technical Assistance II Project (FANTA-2), Acedemy for Educational Development* 2010.
38. Radloff LS. The CES-D scale a self-report depression scale for research in the general population. *Applied psychological measurement* 1977; **1**(3): 385-401.
39. Mollica RF, Caspi-Yavin Y, Bollini P, Truong T, Tor S, Lavelle J. The Harvard Trauma Questionnaire. Validating a cross-cultural instrument for measuring torture, trauma, and posttraumatic stress disorder in Indochinese refugees. *J Nerv Ment Dis* 1992; **180**(2): 111-6.
40. Hayes RJ, Moulton LH. Cluster Randomised Trials: CRC Press; 2009.
41. Fulu E, Jewkes R. Replicating the UN Multi-Country Study on men and violence: Understanding why some men use violence against women and how we can prevent it. Bangkok, Thailand: Partners for Prevention, 2014.
42. Petersen ML, Sinisi SE, van der Laan MJ. Estimation of direct causal effects. *Epidemiology* 2006; **17**(3): 276-84.
43. Patton MQ. Qualitative research: Wiley Online Library; 2005.
44. Wathen CN, MacMillan HL. Interventions for violence against women: scientific review. *Jama* 2003; **289**(5): 589-600.
45. Ramsay J, Rivas C, Feder G. Interventions to reduce violence and promote the physical and psychosocial well-being of women who experience partner violence: A systematic review of controlled evaluations: Final report: Barts and the London, Queen Mary's School of Medicine and Dentistry; 2005.

Figure 1: Flow diagram showing the trial recruitment and follow up at 12 and 24 months

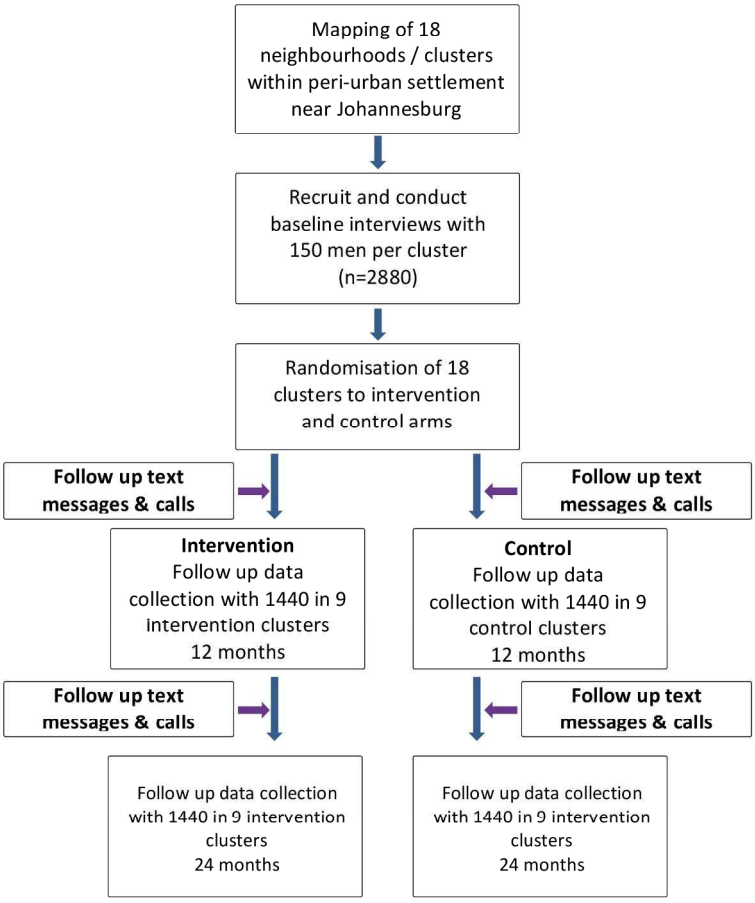

Figure 1: Flow diagram showing the trial recruitment and follow up at 12 and 24 months

833x811mm (72 x 72 DPI)

Figure 2: Power calculation showing a reduction in the prevalence of men's use of violence in the previous 12 months from 12% to 7% with six, seven, eight or nine clusters per arm and approximately 150 participants per cluster

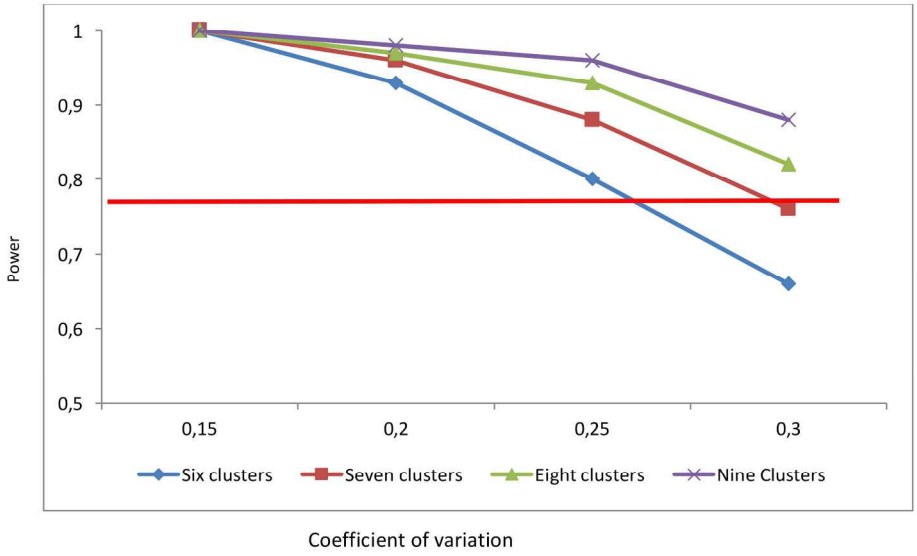

Figure 2: Power calculation showing a reduction in the prevalence of men's use of violence in the previous 12 months from 12% to 7% with six, seven, eight or nine clusters per arm and approximately 150 participants per cluster

832x656mm (72 x 72 DPI)

Figure 3. Schedule of enrolment, interventions, and assessments for the Sonke CHANGE trial

	STUDY PERIOD: January 2016-July 2018						
	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT	*Feb-April 2016*	*April 2016*	*May-Dec 2016*	*Feb-Jul 2017*	*Aug-Dec 2017*	*Jan-Jun 2018*	*July 2018*
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
[Sonke Intervention]			◆—	—	—	—◆	
[Control/standard care]			◆—	—	—	—◆	
ASSESSMENTS:							
[Date of birth, education, housing, food security, income, childhood trauma questionnaire]	X						
[Use of sexual and/or physical violence]	X			X		X	
[Alcohol use, gender attitudes, male controlling behavior, parenting, social cohesion]	X			X		X	
[Partnership characteristics, drug use, depression, PTSD]	X			X		X	

Figure 3. Schedule of enrollment, interventions, and assessments for the Sonke CHANGE trial

733x752mm (72 x 72 DPI)

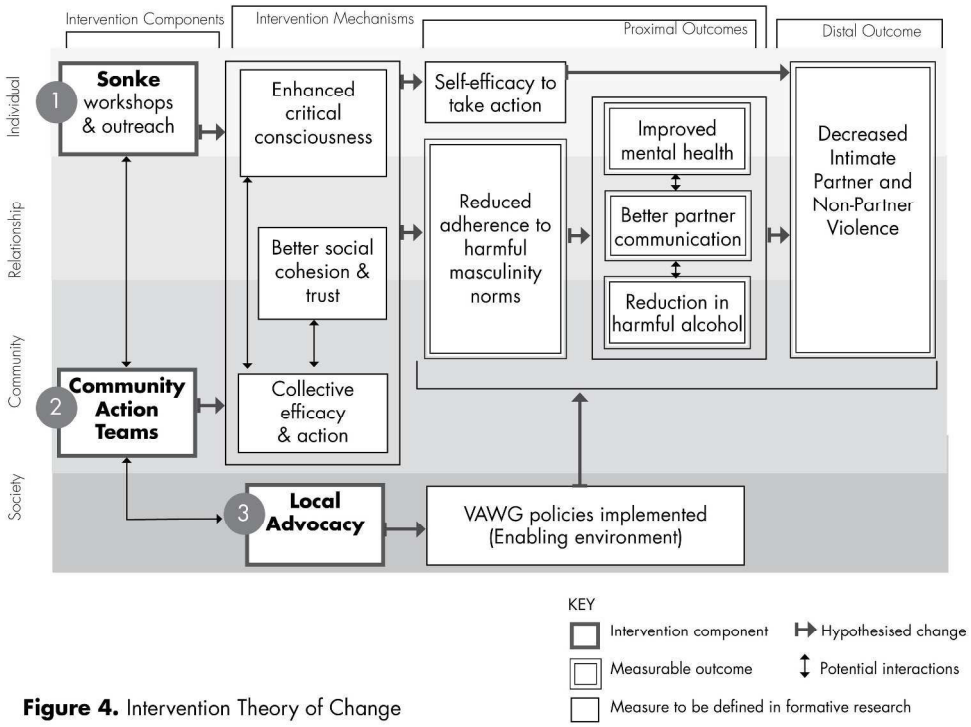

Figure 4. Intervention Theory of Change

Figure 4. Sonke Theory of Change

270x203mm (300 x 300 DPI)

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	____1_____
	2b	All items from the World Health Organization Trial Registration Data Set	____1-13_____
Protocol version	3	Date and version identifier	_____1_____
Funding	4	Sources and types of financial, material, and other support	_____1_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	____1_____
	5b	Name and contact information for the trial sponsor	____1_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	____6_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	____n/a_____

Introduction			
Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	___4-5_____
	6b	Explanation for choice of comparators	___10_____
Objectives	7	Specific objectives or hypotheses	___6_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	___7-8_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	_____6_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	_____6_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_____9-11_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	____n/a_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	____n/a_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	___n/a_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	___11-13_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	___9. Fig 3____

Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	13
Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	7
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	14
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	14
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	14
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	14
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	n/a
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	15
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	14-15

Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	16
Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	16-17
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	17
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	16
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	22
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	n/a
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	21-22
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	n/a
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	19
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	20

Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	19
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	20
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	15
Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	25
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	23
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	n/a
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	23
	31b	Authorship eligibility guidelines and any intended use of professional writers	25
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	23
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	Supplementary materials
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	n/a

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.

BMJ Open

A cluster randomized controlled trial to determine the effect of community mobilization and advocacy on men's use of violence in peri-urban South Africa: Study protocol

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ABSTRACT

Objective: This paper describes the design and methods of a cluster randomized controlled trial to determine the effectiveness of a community mobilization intervention that is designed to reduce the perpetration of violence against women (VAW).

Methods and analysis: A cluster randomized controlled trial (C-RCT) of 9 intervention and 9 control clusters is being carried out in a peri-urban, semi-formal settlement near Johannesburg, South Africa between 2016 and 2018. A community mobilization intervention called Sonke CHANGE is being implemented over 18 months. It comprises advocacy and group activities to engage community members to challenge harmful gender norms and reduce VAW. The intervention is hypothesized to improve equitable masculinities, reduce alcohol use, and ultimately, to reduce VAW. Intervention effectiveness will be determined through an audio computer-assisted questionnaire with self-reported behavioral measures among 2600 men aged between 18 and 40 years at baseline, 12 months and 24 months. The primary trial outcome is men's use of physical and / or sexual violence against women. Secondary outcomes include harmful alcohol use, gender attitudes, controlling behaviors, transactional sex and social cohesion. The main analysis will be intention-to-treat based on the randomization of clusters. A qualitative process evaluation is being conducted alongside the C-RCT. Implementers and men participating in the intervention will be interviewed longitudinally over the period of intervention implementation and observations of the workshops and other intervention activities are being carried out.

Ethics and dissemination: Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee and procedures comply with ethical

recommendations of the United Nations Multi-Country Study on Men and Violence. Dissemination of research findings will take place with local stakeholders and through peer-reviewed publications, with data available upon request or after 5 years of trial completion.

Strengths and limitations of this study:

- There is limited evidence from low- and middle-income countries of what works to prevent men's use violence against women and girls
- Strengths include randomization of clusters after baseline data collection and intention to treat analysis.
- Limitations include risk of contamination across clusters and potential loss-to follow-up of men over 2 years

INTRODUCTION

Violence against women (VAW), including sexual and/or physical violence, is a leading cause of morbidity and mortality among the 35% of women globally who experience it. [1, 2] Prevalence of intimate partner and non-partner violence against women is high in Southern Africa. Large studies among South African men found that 27.5 – 31.8% report enacting physical and / or sexual violence towards partners, [3] and 27.6% of men have ever raped.[4] These high rates of violence against partners and non-partners are consistent with population-based findings from studies among men in other regions globally.[5, 6]

There is a growing consensus that hegemonic masculinities lead to harmful health behaviors, including VAW.[7] Research suggests that men who strictly adhere to dominant norms of masculinity (e.g. toughness, virility, power) are more likely to perpetrate VAW.[6, 8] However, the evidence base for precisely *how* interventions can encourage men to reconstruct masculinities and whether this would result in a reduction of perpetration of VAW is limited. Much of the literature focuses on the problems of masculinity,[9] and evidence from existing programs is restricted to a handful of small interventions.[10, 11] In South Africa two trials with primary outcomes that aimed to reduce the incidence of HIV had some promising results at reducing VAW. The IMAGE trial combined economic intervention with gender training workshops and reported a reduction in women's reports of past year VAW by 51%.[12] Stepping Stones, a series of community-based workshops with women and men, showed a 38% reduction in men's perpetration of violence after two years of follow up.[10]

Sonke Gender Justice (Sonke), a South African nongovernmental organization, has been running gender transformative, community-based programs since 2006. The core Sonke intervention has evolved over more than 10 years and is premised on mobilizing communities to take action against VAW. The activities include a series of group workshops and other reflective activities to challenge harmful gender norms and educate men about gender-based violence and HIV risks.[13, 14] The theory underpinning the intervention is that through community outreach and advocacy, harmful values and practices can be transformed toward gender equity and thereby reduce VAW. Equitable masculine norms manifest through behaviors and attitudes that are considered to reduce the likelihood of VAW (e.g. equality, respect, intimacy, responsibility).[15, 16] The Sonke CHANGE intervention adds to existing Sonke activities by bolstering community action and local advocacy specifically around men's use of VAW. CHANGE stands for "Community Health Action for Norms and Gender Equity" and posits that masculine norms can be progressively transformed through community activities that stimulate personal as well as collective reflection and action.

This type of gender transformative intervention is under-researched,[17] but there is preliminary qualitative evidence though that such an approach is promising.[18, 19] In order to reach global goals of eliminating VAW,[20] it is crucial to understand how multilevel programming may impact men's use of violence. The aim of the cluster randomized controlled trial (C-RCT) is to determine the effectiveness of the Sonke CHANGE intervention to prevent men's use of sexual and or physical violence against an intimate partner and reduce the severity of perpetration by men aged 18 to 40 years living in a peri-urban South African settlement over two years of follow-up.

METHODOLOGY

This trial is funded by the United Kingdom Agency for International Development through What Works to Prevent Violence, a global consortium of research managed by the South African Medical Research Council. What Works had broad input on the scientific and ethical considerations of study design, and has an advisory role in data collection, management, analysis, and interpretation of data. The writing and submission of the report is the decision of the investigative team.

The Consolidated Standards of Reporting Trials (CONSORT) and Standard Protocol Items for Randomized Trials (SPIRIT) guidelines have been followed, and the study protocol adheres to the Standard Protocol Items: Recommendations for Interventional Trials. The protocol is registered with ClinicalTrials.gov (NCT02823288) under the name: Multilevel Intervention for Preventing Men's Use of Violence in Urban South Africa (Sonke CHANGE Trial).

Participants, interventions and outcomes

The trial is being conducted in a semi-formal 'township" located near Johannesburg, South Africa. The peri-urban settlement took form in the mid-1990s, when the fall of apartheid 'pass laws' allowed non-whites to move closer to cities to seek employment. Most residents live in government-subsidized housing and informal tin shacks. Few exact population estimates exist, but most assume the 'township' is now home to between 250 000 and a half million people, including high numbers of migrants from other African countries. Many residents lack access to basic services such as running water, sewerage and rubbish removal. Citizen officials estimate that half the population in the settlement is unemployed.[21]

Recruitment of participants was led by the trial team of trained research assistants. Men who lived in the area for at least 12 months and were 18-40 years old were eligible to be recruited. Men over the age of 40 years are not being prevented from participating in community mobilization or any of the Sonke CHANGE intervention activities but were not be eligible to be recruited for the trial. The study is described as a project about men's lives and relationships, rather than about violence, to prevent undue stigma for study participation.[22]

Trial Design

A two-arm C-RCT is being conducted as shown in Figure 1. Due to the informality of geographic boundaries within the peri-urban settlement, a cluster is defined as a neighborhood bordered by a community landmark such as a church, community hall or communal water source. These landmarks were mapped through transect walks using global positioning systems coordinates obtained on a Samsung Tablet application *Map Coordinates*. The 18 clusters, identified for the purposes of the trial, were evenly spaced throughout the community and contained dwellings falling within a radius of 0.4 kilometers of each community landmark.

Clusters identified for inclusion in the study are not contiguous and each is bordered by a natural boundary (such as a stream) or by a sizeable physical distance of at least 400 metres. While contamination is a concern, spillover effects in this type of C-RCT cannot be perfectly contained. Any intentional or unintentional contamination is being measured through a series of items on the questionnaire that determine participant exposure to specific intervention components. This data will be triangulated with qualitative process evaluation data to provide a contextualized understanding of contamination/spillover effects.

Insert Figure 1 about here

Intervention activities

The Sonke CHANGE Intervention is being implemented over a period of 18 months (April 2016 to November 2017). Sonke Gender Justice is implementing a multi-level approach to stimulate critical reflection among men and promote equitable gender norms and non-violent masculine attitudes and practices. The Sonke core intervention staff comprises a full-time manager and six community mobilisers (3=men, 3=women) recruited from the community where the study is taking place. Two community mobilisers are responsible for three intervention clusters. Intervention activities are comprised of workshops initially run by community mobilisers, mobilization led by Community Action Teams (CATs), and advocacy (see Table 1). Community mobilizers received extensive training over several months, comprised of a manualized curriculum that includes participatory activities, values clarification, and shadowing established mobilisers working in a different community.

Table 1. CHANGE Intervention activities

Activity	*Frequency*	*Target people reached per cluster, per activity*
1. CHANGE Training		
Recruit potential CAT members	Ongoing as needed	15
5 day training	Once off for Community Action Team (CAT) members	15
Individual commitment to action & report-back (community bystander activities)	Monthly	5
Refresher training	Quarterly	12
2. CAT Community mobilization		
Door-to-door campaign	2 x week	60
Street intervention (banner/poster discussion)	2 x week	10
CHANGE Workshops – 2 day training	2 x Month	30
Mini-workshops (1-2 hours) held in local taverns, churches, schools	Weekly	12
Digital stories film screenings	2 x Month	50
Mural paintings	2 x Month	80

Ambush theatre	Monthly	50
Community dialogues	Monthly	80
Debate session (at schools) – community mobiliser	Monthly	30
Most significant change story	Monthly (start at 6 months)	1
Stakeholder meeting (CBOs, Community police forums, community leaders)	2 x week	80
Street soccer – VAW information or debate	Quarterly	15
Open houses to discuss a topic or theme	Quarterly	60
Training local organizations (3 days)	Annually	30
3. Advocacy		
Lobbying	Ongoing	TBD
Marching/protest	Ongoing	TBD
Media advocacy	Ongoing	TBD

Workshops aim to challenge inequitable and harmful ideas about manhood and encourage men to take action to promote equality.[23, 24] They draw on Freirean education pedagogy and principles and promote reflection and a commitment to action.[25, 26] A dedicated workshop curriculum was developed specific to the goals of the Sonke CHANGE intervention, with additional materials created to bolster emphasis on VAW prevention.

Community Action Teams (CATs) are comprised of men and women who mobilize community members on a voluntary basis around issues of gender transformation. CATs are recruited through workshops that are run by community mobilizers. Participants who are particularly interested in the content of the workshops are invited to join a CAT. In practice, CAT members include approximately 20-40 members of the local community, all of whom live in intervention clusters. The process of recruiting and training CAT members occurs on an ongoing basis, depending on retention and planned mobilization activities. CATs are trained through week-long, manualized workshops that are led by Sonke Community Mobilizers. Following training and a process of shadowing the Community Mobilizers (lasting between 1 and 6 months, depending on the skills of the CAT members), CATs initiate a number of activities throughout all 9 intervention clusters, such as workshops,

ambush theatre (spontaneous theatre that occurs on the street), door-to-door educational outreach, and community dialogues. CAT activities aim to reach a large number of people in each community to achieve "saturation" of new ideas and social norms. CATs receive transportation reimbursement but do not receive a salary for their efforts.

Advocacy is undertaken by Sonke staff including community mobilizers, who aim to hold government and other duty bearers to account for VAW prevention. Sonke staff join local community structures such as community policing forums, school governing bodies, hospital committees, church groups, and football-clubs and use their presence to advance community education and local government accountability.

Workshops address hegemonic masculinities on the personal level; CATs address hegemonic masculinity norms at a community level; and advocacy addresses hegemonic masculinity on the level of governance. Together this multilevel approach intends to stimulate critical reflection at the individual, social and political levels.

In the control cluster, communities receive the standard care. This choice of comparator is deemed ethical since little evidence exists for the efficacy and safety of the intervention being tested. Any pre-existing interventions or community-based activities are continuing. However, communities in the control arm are not being intentionally exposed to Sonke CHANGE intervention activities. One caveat is that advocacy may necessarily overlap across cluster boundaries, since it is likely to engage large parts of the peri-urban community. This scientific limitation will be accounted for during follow-up data collection, which asks individuals about their exposure to Sonke advocacy.

Outcome Measures

The long-term goal of the intervention is to reduce men's use of intimate partner and non-partner violence against women. A number of primary and secondary measures have been defined *a priori*.

Primary Outcome Measure: Men's Reported Violence

Men's use of violence towards an intimate partner is measured using an adapted version of the questionnaire from the South African Medical Research Council's Study on Men's Health and Relationships.[6, 27] The questionnaire includes items around emotional abuse, economic abuse, physical violence, and sexual violence. Primary outcomes are defined as dichotomous outcomes: any use of physical violence and/or any use of sexual violence against a partner in the past 12 months. The severity of sexual and / or physical violence use will use the Likert scale responses to violence items.[28]

Secondary Outcome Measures

Harmful alcohol use is measured using the Alcohol Use Disorders Identification Test, a 10-item scale designed to measure alcohol consumption and identify risks for alcohol abuse and dependence.[29]

Perpetration of non-partner rape measured using an adapted version of the questionnaire from the South African Medical Research Council's Study on Men's Health and Relationships.[6, 27]

Gender Attitudes are measured using the Gender Equitable Men's Scale[30] and the Gender Norms scale on whether a man perceives that his community holds those beliefs.[31]

Male Controlling Behaviour is measured using the Sexual Relationship Power and Control scale items.[32] This scale has been validated in South Africa,[33] and has been used by members of our team in previous studies.[34]

Parenting is measured by the Parent-Child Conflict Tactics Scale, a series of items about parental psychological abuse and physical discipline of children.[35]

Transactional sex is measured using the Medical Research Council's standard measure for South Africa. This measures transactional sex among casual partners.[31]

Social cohesion is assessed using a measure from the Stepping Stones questionnaire.[36]

Mental health is measured using multiple scales. Depression is measured using the CES-D, a brief, validated instrument based on the nine diagnostic criteria for DSM-IV depressive disorders [37]. The Harvard Trauma Questionnaire (HTQ) is a cross-cultural instrument for measuring symptoms associated with post-traumatic stress disorder.[38]

Covariates

Partnership characteristics include basic demographics about sexual partners and sexual behaviour from the Stepping Stones questionnaire.[36]

Socio-economic status is assessed using items from the United Nations Multi-country Study around education, marital status, household size, and monthly income.

Food security is measured using the Household Hunger Scale, a 3-item measure developed by the USAID-funded Food and Nutrition Technical Assistance (FANTA) project.[39]

Drug use is measured using a single question from the United Nations Multi-country Study around past year use: "How many times have you used drugs in the last 12 months?"

Participant views and participation in violence-related campaigns is assessed using items from the Gender Links survey.[31] Exposure to the intervention prior to baseline and in both intervention and control communities are being measured through a series of questions that ask about awareness of Sonke Gender Justice, participation in workshops and other activities.

Power estimates

Little data is available to estimate incidence of men's use of VAW in South Africa. However, one population-based study that used a representative sample by Gender Links in Gauteng Province provides a point estimate of past-year use of violence among men. In the Gender Links study, 12% of men used physical or sexual violence towards a partner in the past 12 months.[31] Thus, based on 12% past year prevalence, we can estimate the study's power to detect a 5% difference if VAW decreases to 7%. The power calculation is based on 150 participants per cluster in 18 clusters. A 20% adjustment for potential loss to follow up increases to 180 the total number of men to be recruited in each cluster with a total sample size of 2880. Figure 2 shows the power calculations based on Moulton and Hayes (2009) for 6, 7, 8 and 9 clusters per arm with a coefficient of variation (k) ranging between 5% and 50%.[40] Data will be collected at three time points: baseline, 12 month and 24 months.

[Insert Figure 2 about here]

Assignment of intervention

Randomisation of clusters into the intervention or control arm was undertaken after the baseline data collection was completed. See Figure 3 for the timing of allocation and assessments.

[Insert Figure 3 about here]

All cluster names were printed on equal sized pieces of paper and the randomisation was performed at a public event. The event was held with local leadership, trial researchers and Sonke staff in a public setting to ensure randomization is transparent to the community. Each local leader chose one cluster name from a bag until nine clusters were allocated to the

intervention arm. Clusters cannot be blinded to their study arm allocation after the initial data collection, nor can intervention implementers be blinded to arm allocation.

Participant enrollment

Study enrollment was initiated through a series of community meetings held in each cluster and door-to-door recruitment of men by trial staff. Men in the 18 clusters were invited to take part in a written informed consent process and thereafter asked to complete a Locator Form by a trained field worker. The Locator Form is the primary method of participant retention, and has information about the participant's dwelling and phone numbers. Locator Form data is stored separately from any other participant data to ensure confidentiality.

Data collection, management and analysis

Data collection occurs in private, confidential locations such as a community hall, or yard identified in each cluster. Data collection is facilitated by trained interviewers, and conducted in the language of participant choice (English, isiZulu, Tsonga, or Sepedi). Interviewers are using an electronic data system called Open Data Kit on 7-inch Samsung tablet computers that operate on the Android platform. These tablet computers are inexpensive and easy-to-carry, and allow ease of data collection. Electronic data collection provides a standardized method that minimizes user bias and improves data quality as it precludes data entry of paper forms. Security of data can be improved through use of electronic data collection (versus using paper forms), since data is uploaded to an encrypted server at the end of each day. The server is housed at the university and has been purpose-built for this study.

We are using audio-computer assisted data collection (ACASI) since sensitive questions around violence can be sensitive and it is ethically challenging to handle disclosure.[41] Use of ACASI prevents complex ethical issues because no interviewer or researcher can examine

responses to illegal questions until the data is de-identified. This inability to see individual data is important for questions around rape and physical or sexual mistreatment of children, since South African law requires mandatory reporting of these types of criminal activities. ACASI allows important data to be collected about legal and illegal activity while ensuring anonymity and confidentiality. Of note, the additional anonymity of ACASI may also lead to more accurate reporting of VAW by men since there would be no social desirability bias typically associated with interviewer-administered questionnaires.

Community Advisory Board

Prior to starting data collection, the team set up a community advisory board (CAB) comprising local leadership. The members include non-governmental organizations, local residents, and ward councilors (local political representatives). Once sensitized to the trial and intervention, the CAB introduced the study, the intervention, the ethical considerations of participating, and the intended outcomes to people in the community. This serves as an opportunity to set expectations around reporting back findings to the community.

Data management and statistical analyses

Data from the baseline interviews and follow-up interview data will be abstracted from Open Data Kit databases built specifically for this study. Procedures to promote data quality include range and logical checks built into Open Data Kit and running additional error checks after data abstraction.

The main analysis will be intention-to-treat based on the randomization of clusters. The period prevalence of violence perpetration over 24 months of follow-up will be calculated.

Men's use of physical and/or sexual IPV over the previous 12 months among the intervention and control clusters will be compared as the primary trial outcome.

Since allocation to the intervention or control arms was by cluster, all statistical assessments of variability will use the cluster as the unit of analysis. Adjusted proportions of men reporting sexual and or physical IPV perpetration in the intervention group relative to the control group will be compared, by comparison of observed and expected prevalence in each cluster. Covariates in the model will include cluster prevalence (calculated using cluster means) of men's use of IPV at baseline, socio-demographic characteristics, relationship characteristics, mental health measures, and attitudinal variables.

Analyses for other primary and secondary outcomes will proceed similarly, with appropriate choices of model for outcome type. A sensitivity analysis will be conducted using individual level data with cluster as a random effect, generalized linear mixed model (GLMM) correcting for small number of clusters and adjusting for baseline variables such as IPV. We will also make preliminary assessments of degree of mediation in models for primary outcomes via inclusion of mediating factors, with assessment of direct and indirect intervention effects of key mediating variables.[42]

Additional analyses will focus on assessing the effects of the intervention on mediating factors such as harmful alcohol use, partner communication and collective efficacy as indicated in the intervention Theory of Change (see Figure 4). Analyses for mediating variables will either treat scores as continuous measures or categorise them according to clinical cut-offs. Initial comparisons will be based on group-specific descriptive summaries of observed outcomes and tests comparing outcomes between groups (t-tests for parametric or

Wilcoxon Mann-Whitney/Wilcoxon Signed Rank tests for nonparametric data; chi-squared for categorical data). We will also use multivariable models regression methods to compare outcomes between groups while controlling for baseline characteristics. ***[Insert Figure 4 about here]***

Process Evaluation

A process evaluation employs a research design that is qualitative and longitudinal over the period of the trial implementation, 2016-2018. It is designed to collect data that enables rich description and captures the subjective experiences of people involved in the Sonke CHANGE intervention as the intervention unfolds over time.

Data collection

A range of data collection techniques is being used for the process evaluation. In-depth interviews are conducted with stakeholders (Sonke managers [n = 5], trial investigators [n=3], and community leaders [n=5]); implementers (mobilisers [n=5], CAT members [n=5], and fieldworkers [n=5]); and research participants [n=10]. In total, 38 participants are being interviewed using a semi-structured topic guide. Participants are asked questions regarding the intervention implementation, contextual factors that may shape primary and secondary outcomes, and experiences in the intervention.

Maximum variation sampling is used in order to ensure a wide range of perspectives are represented among stakeholders, implementers and participants.[43] This enables the collection of data that provides insights from different perspectives and enables analysis of common themes and divergent opinions across groups of actors.

Over the course of the Sonke CHANGE intervention each of the 38 interviewees are being interviewed on multiple occasions: stakeholders twice and implementers and participants on three occasions. In total 101 interviews will be conducted. The collection of longitudinal interview data will enable analysis of shifts in perspectives and insights into how transformation might occur through participation in the intervention.

Participant-observation is collected in a semi-structured manner by a process evaluation researcher with expertise in ethnographic methods. The researcher is purposively attending at least one of each type of intervention activity. Participant-observation will ensure unanticipated developments in the intervention are captured (e.g. an unplanned intervention activity). Participant-observation data will provide insight into the contextual factors that impede and facilitate the implementation of the Sonke CHANGE trial.

Data analysis

Analysis of process evaluation data will be iterative and will be managed using qualitative software. Content analysis will be used to describe the processes of participant behavior change over time in order to determine what kinds of changes occur in men participating in intervention activities. A secondary focus will be placed on analyzing theoretical themes that are identified across, and between, the qualitative data set in order to explore how and why identified changes in perceptions, beliefs or behavior occur. A final focus will be placed on interpreting findings in order to explain the nature and meaning of changes in perception, belief or behaviour as well as to further theory development and determine the transferability of the study's findings to other contexts.

Ethics and dissemination

Ethical approval was obtained from the University of the Witwatersrand Human Research Ethics Committee. Changes to the protocol are submitted to this body, and the funder is made aware of relevant amendment approvals after they are obtained.

Researchers received intensive training on VAW, the study protocol, collecting sensitive information, and ensuring data quality and participant confidentiality. Informed consent procedures comply with ethical recommendations of the University of Witwatersrand and of the United Nations Multi-Country Study on Men and Violence.[41] Prospective participants were informed that they do not have to participate in the trial unless they are happy with the trial procedures and understand what the trial is about. All participants were told that participation is voluntary, that they may withdraw at any stage, skip any question in the research and that there are no adverse effects should they decide not to participate. For the success of the project we require all research participants to agree in principle to multiple interviews (i.e. baseline, 12 months and 24 months) - although they may change their mind.

The participant information leaflets and consent forms are written in simple English, however to enhance understanding, the explanation and discussion may be in isiZulu, Sepedi, Tsonga, or English depending on the participant's language preference. A researcher was present throughout the informed consent process and clarified any questions the participants were not clear about. Once they are fully informed about the study, they were asked to sign informed consent for the interview. Participants also are asked for written informed consent to have their interview digitally recorded. Anonymity is important because of the sensitive nature of some of the questions. All questionnaires are identified by study identification numbers that are directly assigned by the electronic data system. Participants are reimbursed for their time

to participate in the study. An amount of R50 (approximately US $3.50) was paid to participants at the baseline data collection.

Participants who report sexual violence perpetrated against either partners or non-partners are not asked the age of the woman. South African law requires mandatory reporting of violence perpetrated against a minor (under the age of 18 years). Participants were informed during the consent process that if they disclose that they have perpetrated violence against a woman to the research assistant that the incident may need to be reported to the police. However, since research assistants do not actively ask any of the questionnaire items, the opportunities for participants to disclose illegal behaviors are reduced.

Should the intervention or research teams become aware of any women who have experienced partner or non-partner violence, a protocol is in place to refer women to local organizations that provide counseling and support for survivors. Should any men disclose personal experiences of violence or be supporting family members who have experienced violence similar referrals for counseling and support are made. The list of referral organizations was developed in consultation with members of the Community Advisory Board to ensure that services are accessible by community members and actively able to take new clients.

Adverse Reporting

In social and behavioral trials, it is important for researchers to 'go beyond' typical medical reporting (which includes only physical health outcomes like hospitalization or mortality) and report on social harms. We will take the most conservative approach to reporting and include

all potential social harms within our definition of adverse events, as noted in italics. **Adverse Events** (AEs) are any untoward medical *or social* occurrence that may present during intervention but which does not necessarily have a causal relationship with this *project.* AEs include risks to participant or fieldworker safety and any breach of confidentiality. **Serious Adverse Events** are any untoward medical *or social* occurrence that results in death or significant disability or *incapacity (including incarceration).* SAEs may also include civil unrest or natural disaster in a study site that has the potential to put at serious risk the interviewers, participants or data quality. All reporting is following protocol established by the University of Witwatersrand Ethics Committee.

Data Monitoring

A data monitoring committee was not established for this trial since the intervention is implemented at the community level, limiting the ability of an outside body to determine a statistical or ethical rationale for stopping rules. The Community Advisory Board does serve as a local accountability mechanism for data at baseline and endline. The scientific steering committee of What Works to Prevent Violence has access to all study protocols and conducts annual checks of data quality and scientific progress. However, unlike some cluster randomized trials, there is not a dedicated data monitoring committee, which may be viewed as a weakness of this study design.

Dissemination

The final trial dataset will be made accessible to trial investigators for a period of five years. During this time, scholarly dissemination will take place through peer-reviewed journals and community dissemination will occur through a series of workshops with key community

stakeholders and members of the network of nongovernmental organizations working in the area to address VAW and children. After five years, the trial dataset will be made available to other researchers through an online portal managed by the What Works to Prevent Violence program.

DISCUSSION

There are many well-documented efforts to reduce violence against women from industrialised countries in North America and Europe [44, 45], with limited evidence from low and middle-income country settings. Many of the evaluated interventions have focused on the response to VAW rather than on primary prevention. Interventions that address the response to VAW have shown impact on physical and mental health outcomes for women but there is limited evidence that these interventions reduce violence.

There are limitations inherent to the design of the C-RCT. Primary and secondary outcomes are self-reported which could result in either over- or under-reporting. It is possible that the self-reporting bias will be different in intervention and control clusters. Men in the intervention clusters may under-report use of violence against women at follow up due to exposure to the intervention and social desirability bias. A strength of the study is that we are collecting longitudinal qualitative data through the process evaluation which will allow for triangulation between different components of the study. However, we are not collecting data from female partners of male participants, due to the safety risks associated with such dyadic data collection. Therefore, like many studies in the violence field, the primary trial outcome will be based on self-reported measures.

The risk of contamination is high due to the close physical proximity of the clusters and the nature of the intervention, which includes community mobilization and advocacy elements. In addition, our formative research has revealed that men's movement within the 'township' is fairly common, which means that over the two years of follow up men may move from an intervention to a control cluster or vice versa. Our analysis will be based on intention to treat to address the movement of men across clusters. We recruited participants and then randomized the clusters after baseline data collection. However, once the intervention activities commence it will no longer be possible to blind participants or implementers to which arm of the cluster they have been randomized. As with all longitudinal studies, loss to follow up is a potential study limitation. Efforts will be made to collect different types of contact information of participants as well as up to four close friends or family members. The two years of follow up data collection may be too short to measure an effect of the intervention since the recent use of violence is asked for the past 12 months. However, we believe that if the intervention is delivered as planned that changes in the primary outcome are possible.

The Sonke CHANGE trial will contribute to the limited body of evidence from low- and middle-income countries of what works to prevent violence against women and girls. It will contribute to a growing set of studies that have explored whether gender transformative approaches work to reduce VAW. The trial together with the process evaluation will provide insight on whether the hypothesized pathways to change are relevant and appropriate. Moreover, we will gain insight into how change happens, if at all. Identifying and measuring interventions for addressing men's use of violence against women is essential if we are to ensure the health and wellbeing of women, children, and men themselves.

Acknowledgements

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Competing interests: None of the authors have any competing interests

Author contributions

NC: conceptualized the study together with AH and AP, wrote the first draft of the manuscript

AH: conceptualized the project together with NC and AP; made substantial contributions to the writing of the manuscript

RM: refined the process evaluation and contributed to the description of the process evaluation in the manuscript

DP, DR, AP and AA: developed and refined the Sonke intervention which the C-RCT is evaluating and commented on the manuscript

Data sharing

Data will be made available via the funder UKAID once the final results of the study are published.

1. WHO. Global and regional estimates of violence against women: prevalence and health effects of intimate partner violence and non-partner sexual violence. Geneva: World Health Organization, 2013.
2. Devries KM, Mak JY, Garcia-Moreno C, et al. The global prevalence of intimate partner violence against women. Science 2013; 340(6140): 1527-8.
3. Dunkle KL, Jewkes RK, Nduna M, et al. Perpetration of partner violence and HIV risk behaviour among young men in the rural Eastern Cape, South Africa. AIDS 2006; 20(16): 2107-14.
4. Jewkes R, Sikweyiya Y, Morrell R, Dunkle K. Gender inequitable masculinity and sexual entitlement in rape perpetration South Africa: findings of a cross-sectional study. PLoS One 2011; 6(12): e29590.
5. Barker G, Contreras JM, Heilman B, Singh AK, Verma RK, Nascimento M. Evolving Men: Initial Results from the International Men and Gender Equality Survey (IMAGES. Washington,D.C.: International Centerfor Research on Women (ICRW) and Instituto Promundo, 2011.
6. Fulu E, Warner X, Miedema S, Jewkes R, Roselli T, Lang J. Why do some men use violence against women and how can we prevent it? Findings from the UN Multi-country study on men and violene in Asia and the Pacific. Bangkok: UNDP, UNFPA, UN Women, UNV, 2013.
7. Jewkes R, Morrell R. Gender and sexuality: emerging perspectives from the heterosexual epidemic in South Africa and implications for HIV risk and prevention. J Int AIDS Soc 2010; 13: 6.
8. Santana MC, Raj A, Decker MR, La Marche A, Silverman JG. Masculine gender roles associated with increased sexual risk and intimate partner violence perpetration among young adult men. J Urban Health 2006; 83(4): 575-85.
9. Mankowski ES, Maton KI. A community psychology of men and masculinity: historical and conceptual review. Am J Community Psychol 2010; 45(1-2): 73-86.
10. Jewkes R, Nduna M, Levin J, et al. Impact of stepping stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial.[see comment]. BMJ 2008; 337: a506.
11. Kalichman SC, Simbayi LC, Cloete A, et al. Integrated gender-based violence and HIV Risk reduction intervention for South African men: results of a quasi-experimental field trial. Prevention Science 2009; 10(3): 260-9.
12. Pronyk PM, Hargreaves JR, Kim JC, et al. Effect of a structural intervention for the prevention of intimate-partner violence and HIV in rural South Africa: a cluster randomised trial. Lancet 2006; 368(9551): 1973-83.
13. Van den Berg W, Hendricks L, Hatcher A, Peacock D, Godana P, Dworkin S. 'One Man Can': shifts in fatherhood beliefs and parenting practices following a gender-transformative programme in Eastern Cape, South Africa. Gender & Development 2013; 21(1): 111-25.
14. Peacock RD, Reneke PA, Forney GP. CFAST-consolidated model of fire growth and smoke transport (version 6) user's guide: Citeseer; 2013.
15. Connell RW. Gender and power: Society, the person and sexual politics: John Wiley & Sons; 2014.
16. Shefer T. From boys to men: Social constructions of masculinity in contemporary society: Juta and Company Ltd; 2007.

17. What Works to Prevent Violence. Summary of the Evidence and Research Agenda for What Works: A Global Programme to Prevent Violence against Women and Girls. London: UKAid, 2014.
18. Dworkin SL, Hatcher AM, Colvin C, Peacock D. Impact of a gender-transformative HIV and antiviolence program on gender ideologies and masculinities in two rural, South African communities. Men and masculinities 2013; 16(2): 181-202.
19. Hatcher AM, Colvin CJ, Ndlovu N, Dworkin SL. Intimate partner violence among rural South African men: alcohol use, sexual decision-making, and partner communication. Cult Health Sex 2014; 16(9): 1023-39.
20. Garcia-Moreno C, Amin A. The sustainable development goals, violence and women's and children's health. Bull World Health Organ 2016; 94(5): 396-7.
21. Mahajan S. Economic of South African townships: special focus on Diepsloot. Washington DC: World Bank Group, 2014.
22. Jewkes R, Dartnall E, Sikweyiya Y. Ethical and Safety Recommendations for Research on the Perpetration of Sexual Violence. Pretoria, South Africa: Sexual Violence Research Initiative, Medical Research Council; 2012.
23. Courtenay WH. Constructions of masculinity and their influence on men's well-being: a theory of gender and health. Soc Sci Med 2000; 50(10): 1385-401.
24. Messner MA. Politics of masculinities: Men in movements: Sage Publications, Inc; 1997.
25. Freire P. Pedagogy of the Oppressed. New York: Continuum; 1970.
26. Freire P. Education for Critical Consciousness. New York: Continuum; 1973.
27. Jewkes R, Sikweyiya Y, Morrell R, Dunkle K. The relationship between intimate partner violence, rape and HIV amongst South African men: a cross-sectional study. PLoS One 2011; 6(9): e24256.
28. Tsai AC, Tomlinson M, Comulada WS, Rotheram-Borus MJ. Intimate Partner Violence and Depression Symptom Severity among South African Women during Pregnancy and Postpartum: Population-Based Prospective Cohort Study. PLoS Med 2016; 13(1): e1001943.
29. Saunders JB, Aasland OG, Babor TF, de la Fuente JR, Grant M. Development of the Alcohol Use Disorders Identification Test (AUDIT): WHO Collaborative Project on Early Detection of Persons with Harmful Alcohol Consumption--II. Addiction 1993; 88(6): 791-804.
30. Pulerwitz J, Barker G. Measuring attitudes towards gender norms among young men in Brazil: Development and psychometric evaluation of the GEM scale. Men and Masculinities 2008; 10: 322-38.
31. MRC. War at Home: Preliminary findings of the Gauteng Gender Violence Prevalence Study Johannesburg,: Gender Links and the Medical Research Council, 2010.
32. Pulerwitz J, Amaro H, De Jong W, Gortmaker SL, Rudd R. Relationship power, condom use and HIV risk among women in the USA. AIDS Care 2002; 14(6): 789-800.
33. Dunkle KL, Jewkes RK, Brown HC, Gray GE, McIntryre JA, Harlow SD. Gender-based violence, relationship power, and risk of HIV infection in women attending antenatal clinics in South Africa. Lancet 2004; 363(9419): 1415-21.
34. Hatcher AM, Tsai AC, Kumbakumba E, et al. Sexual Relationship Power and Depression among HIV-Infected Women in Rural Uganda. PloS one 2012; 7(12): e49821.
35. Straus MA, Hamby SL, Finkelhor D, Moore DW, Runyan D. Identification of child maltreatment with the Parent-Child Conflict Tactics Scales: Development and psychometric data for a national sample of American parents. Child abuse & neglect 1998; 22(4): 249-70.

36. Jewkes R, Nduna M, Levin J, et al. Impact of stepping stones on incidence of HIV and HSV-2 and sexual behaviour in rural South Africa: cluster randomised controlled trial. Bmj 2008; 337: a506.
37. Radloff LS. The CES-D scale a self-report depression scale for research in the general population. Applied psychological measurement 1977; 1(3): 385-401.
38. Mollica RF, Caspi-Yavin Y, Bollini P, Truong T, Tor S, Lavelle J. The Harvard Trauma Questionnaire. Validating a cross-cultural instrument for measuring torture, trauma, and posttraumatic stress disorder in Indochinese refugees. J Nerv Ment Dis 1992; 180(2): 111-6.
39. Deitchler M, Ballard T, Swindale A, Coates J. Validation of a measure of household hunger for cross-cultural use. Washington, DC: Food and Nurtrition Technical Assistance II Project (FANTA-2), Acedemy for Educational Development 2010.
40. Hayes RJ, Moulton LH. Cluster Randomised Trials: CRC Press; 2009.
41. Fulu E, Jewkes R. Replicating the UN Multi-Country Study on men and violence: Understanding why some men use violence against women and how we can prevent it. Bangkok, Thailand: Partners for Prevention, 2014.
42. Petersen ML, Sinisi SE, van der Laan MJ. Estimation of direct causal effects. Epidemiology 2006; 17(3): 276-84.
43. Patton MQ. Qualitative research: Wiley Online Library; 2005.
44. Wathen CN, MacMillan HL. Interventions for violence against women: scientific review. Jama 2003; 289(5): 589-600.
45. Ramsay J, Rivas C, Feder G. Interventions to reduce violence and promote the physical and psychosocial well-being of women who experience partner violence: A systematic review of controlled evaluations: Final report: Barts and the London, Queen Mary's School of Medicine and Dentistry; 2005.

Figure legends:

Figure 1: Flow diagram showing trial recruitment and follow up as 12 and 24 months

Figure 2: Power calculation showing a reduction in the prevalence of men's use of intimate partner violence in the previous 12 months from 12% to 7% with six, seven, eight or nine clusters per arm and approximately 150 men per cluster

Figure 3: Schedule of enrolment, intervention and assessments for the Sonke CHANGE Trial

Figure 4. Sonke CHANGE Trial Theory of Change

Figure 1: Flow diagram showing the trial recruitment and follow up at 12 and 24 months

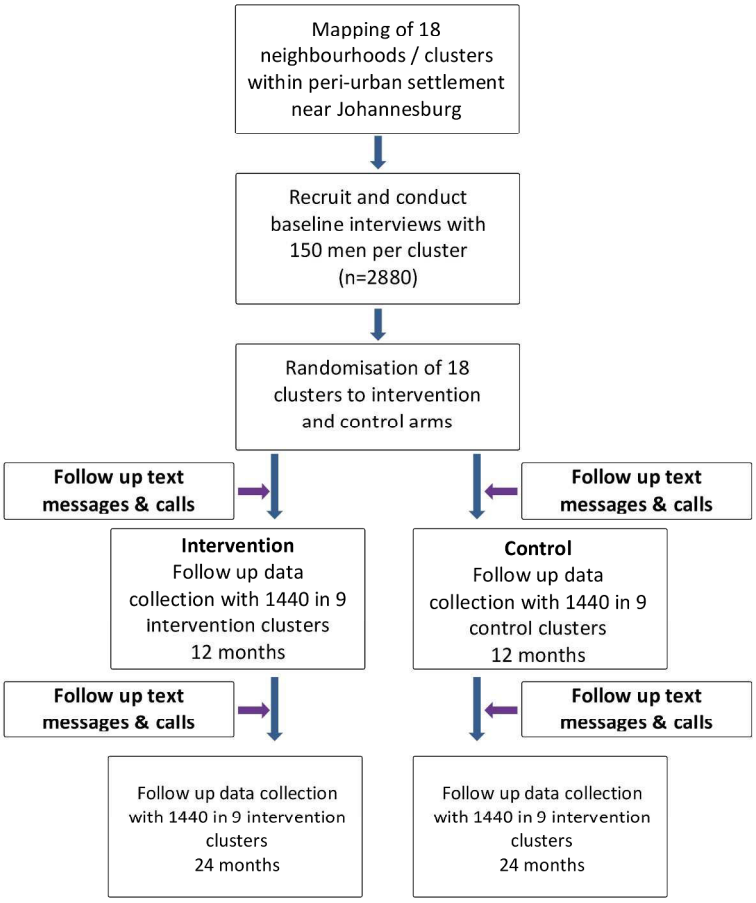

Figure 1: Flow diagram showing trial recruitment and follow up as 12 and 24 months

Figure 2: Power calculation showing a reduction in the prevalence of men's use of violence in the previous 12 months from 12% to 7% with six, seven, eight or nine clusters per arm and approximately 150 participants per cluster

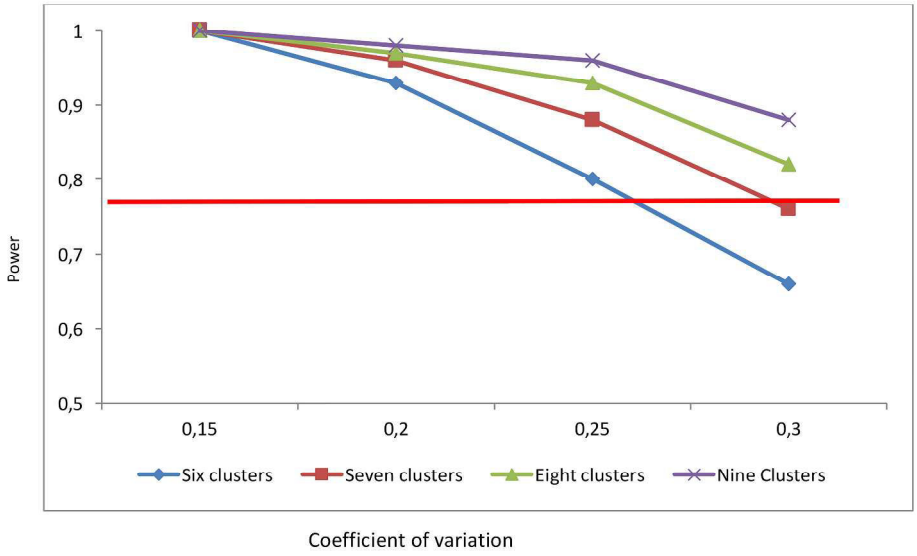

Figure 2: Power calculation showing a reduction in the prevalence of men's use of intimate partner violence in the previous 12 months from 12% to 7% with six, seven, eight or nine clusters per arm and approximately 150 men per cluster

Figure 3. Schedule of enrolment, interventions, and assessments for the Sonke CHANGE trial

	STUDY PERIOD: January 2016-July 2018						
	Enrolment	Allocation	Post-allocation				Close-out
TIMEPOINT	*Feb-April 2016*	*April 2016*	*May-Dec 2016*	*Feb-Jul 2017*	*Aug-Dec 2017*	*Jan-Jun 2018*	*July 2018*
ENROLMENT:							
Eligibility screen	X						
Informed consent	X						
Allocation		X					
INTERVENTIONS:							
[Sonke Intervention]			◆	—	—	◆	
[Control/standard care]			◆	—	—	◆	
ASSESSMENTS:							
[Date of birth, education, housing, food security, income, childhood trauma questionnaire]	X						
[Use of sexual and/or physical violence]	X			X		X	
[Alcohol use, gender attitudes, male controlling behavior, parenting, social cohesion]	X			X		X	
[Partnership characteristics, drug use, depression, PTSD]	X			X		X	

Figure 3: Schedule of enrolment, intervention and assessments for the Sonke CHANGE Trial

176x180mm (300 x 300 DPI)

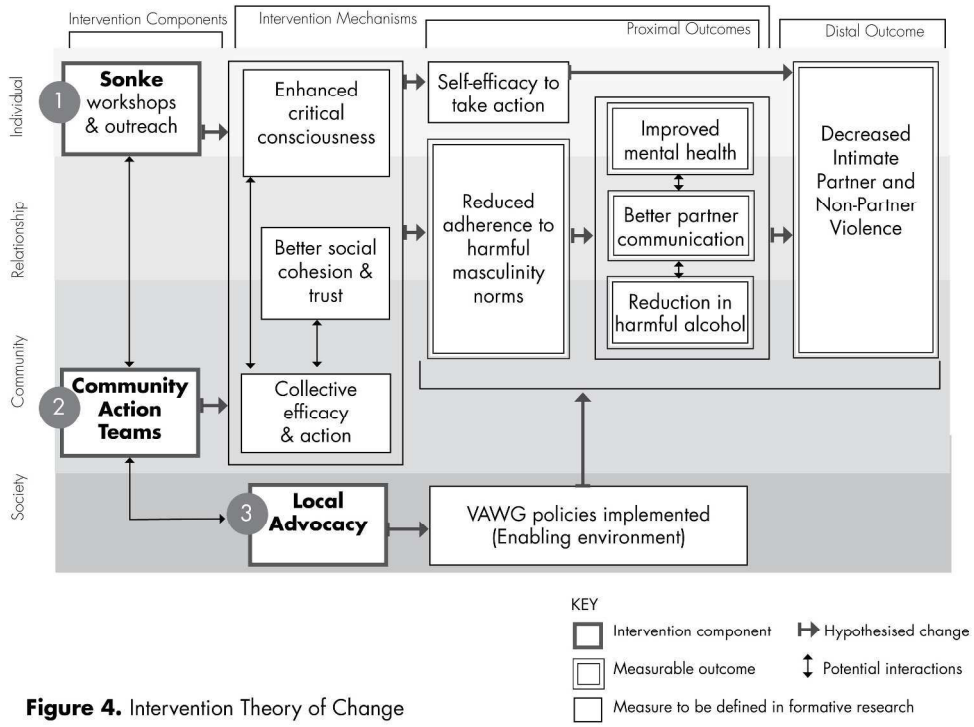

Figure 4. Intervention Theory of Change

Figure 4. Sonke CHANGE Trial Theory of Change

270x203mm (300 x 300 DPI)

SPIRIT
STANDARD PROTOCOL ITEMS: RECOMMENDATIONS FOR INTERVENTIONAL TRIALS

SPIRIT 2013 Checklist: Recommended items to address in a clinical trial protocol and related documents*

Section/item	Item No	Description	Addressed on page number
Administrative information			
Title	1	Descriptive title identifying the study design, population, interventions, and, if applicable, trial acronym	___1_____
Trial registration	2a	Trial identifier and registry name. If not yet registered, name of intended registry	____1_____
	2b	All items from the World Health Organization Trial Registration Data Set	____1-13_____
Protocol version	3	Date and version identifier	_____1_____
Funding	4	Sources and types of financial, material, and other support	_____1_____
Roles and responsibilities	5a	Names, affiliations, and roles of protocol contributors	____1_____
	5b	Name and contact information for the trial sponsor	____1_____
	5c	Role of study sponsor and funders, if any, in study design; collection, management, analysis, and interpretation of data; writing of the report; and the decision to submit the report for publication, including whether they will have ultimate authority over any of these activities	____6_____
	5d	Composition, roles, and responsibilities of the coordinating centre, steering committee, endpoint adjudication committee, data management team, and other individuals or groups overseeing the trial, if applicable (see Item 21a for data monitoring committee)	____n/a_____
Introduction			

Background and rationale	6a	Description of research question and justification for undertaking the trial, including summary of relevant studies (published and unpublished) examining benefits and harms for each intervention	___4-5_____
	6b	Explanation for choice of comparators	___10_____
Objectives	7	Specific objectives or hypotheses	___6_____
Trial design	8	Description of trial design including type of trial (eg, parallel group, crossover, factorial, single group), allocation ratio, and framework (eg, superiority, equivalence, noninferiority, exploratory)	___7-8_____
Methods: Participants, interventions, and outcomes			
Study setting	9	Description of study settings (eg, community clinic, academic hospital) and list of countries where data will be collected. Reference to where list of study sites can be obtained	_____6_____
Eligibility criteria	10	Inclusion and exclusion criteria for participants. If applicable, eligibility criteria for study centres and individuals who will perform the interventions (eg, surgeons, psychotherapists)	_____6_____
Interventions	11a	Interventions for each group with sufficient detail to allow replication, including how and when they will be administered	_____9-11_____
	11b	Criteria for discontinuing or modifying allocated interventions for a given trial participant (eg, drug dose change in response to harms, participant request, or improving/worsening disease)	____n/a_____
	11c	Strategies to improve adherence to intervention protocols, and any procedures for monitoring adherence (eg, drug tablet return, laboratory tests)	____n/a_____
	11d	Relevant concomitant care and interventions that are permitted or prohibited during the trial	___n/a_____
Outcomes	12	Primary, secondary, and other outcomes, including the specific measurement variable (eg, systolic blood pressure), analysis metric (eg, change from baseline, final value, time to event), method of aggregation (eg, median, proportion), and time point for each outcome. Explanation of the clinical relevance of chosen efficacy and harm outcomes is strongly recommended	___11-13_____
Participant timeline	13	Time schedule of enrolment, interventions (including any run-ins and washouts), assessments, and visits for participants. A schematic diagram is highly recommended (see Figure)	___9. Fig 3____
Sample size	14	Estimated number of participants needed to achieve study objectives and how it was determined, including clinical and statistical assumptions supporting any sample size calculations	____13_____

Recruitment	15	Strategies for achieving adequate participant enrolment to reach target sample size	_____7_____
Methods: Assignment of interventions (for controlled trials)			
Allocation:			
Sequence generation	16a	Method of generating the allocation sequence (eg, computer-generated random numbers), and list of any factors for stratification. To reduce predictability of a random sequence, details of any planned restriction (eg, blocking) should be provided in a separate document that is unavailable to those who enrol participants or assign interventions	____14_____
Allocation concealment mechanism	16b	Mechanism of implementing the allocation sequence (eg, central telephone; sequentially numbered, opaque, sealed envelopes), describing any steps to conceal the sequence until interventions are assigned	___14_____
Implementation	16c	Who will generate the allocation sequence, who will enrol participants, and who will assign participants to interventions	____14_____
Blinding (masking)	17a	Who will be blinded after assignment to interventions (eg, trial participants, care providers, outcome assessors, data analysts), and how	____14_____
	17b	If blinded, circumstances under which unblinding is permissible, and procedure for revealing a participant's allocated intervention during the trial	____n/a_____
Methods: Data collection, management, and analysis			
Data collection methods	18a	Plans for assessment and collection of outcome, baseline, and other trial data, including any related processes to promote data quality (eg, duplicate measurements, training of assessors) and a description of study instruments (eg, questionnaires, laboratory tests) along with their reliability and validity, if known. Reference to where data collection forms can be found, if not in the protocol	____15_____
	18b	Plans to promote participant retention and complete follow-up, including list of any outcome data to be collected for participants who discontinue or deviate from intervention protocols	____14-15_____
Data management	19	Plans for data entry, coding, security, and storage, including any related processes to promote data quality (eg, double data entry; range checks for data values). Reference to where details of data management procedures can be found, if not in the protocol	____16_____

Statistical methods	20a	Statistical methods for analysing primary and secondary outcomes. Reference to where other details of the statistical analysis plan can be found, if not in the protocol	___16-17_____
	20b	Methods for any additional analyses (eg, subgroup and adjusted analyses)	___17_____
	20c	Definition of analysis population relating to protocol non-adherence (eg, as randomised analysis), and any statistical methods to handle missing data (eg, multiple imputation)	____16_____
Methods: Monitoring			
Data monitoring	21a	Composition of data monitoring committee (DMC); summary of its role and reporting structure; statement of whether it is independent from the sponsor and competing interests; and reference to where further details about its charter can be found, if not in the protocol. Alternatively, an explanation of why a DMC is not needed	____22_____
	21b	Description of any interim analyses and stopping guidelines, including who will have access to these interim results and make the final decision to terminate the trial	____n/a_____
Harms	22	Plans for collecting, assessing, reporting, and managing solicited and spontaneously reported adverse events and other unintended effects of trial interventions or trial conduct	___21-22_____
Auditing	23	Frequency and procedures for auditing trial conduct, if any, and whether the process will be independent from investigators and the sponsor	____n/a_____
Ethics and dissemination			
Research ethics approval	24	Plans for seeking research ethics committee/institutional review board (REC/IRB) approval	_____19_____
Protocol amendments	25	Plans for communicating important protocol modifications (eg, changes to eligibility criteria, outcomes, analyses) to relevant parties (eg, investigators, REC/IRBs, trial participants, trial registries, journals, regulators)	____20_____
Consent or assent	26a	Who will obtain informed consent or assent from potential trial participants or authorised surrogates, and how (see Item 32)	____19_____
	26b	Additional consent provisions for collection and use of participant data and biological specimens in ancillary studies, if applicable	____20_____
Confidentiality	27	How personal information about potential and enrolled participants will be collected, shared, and maintained in order to protect confidentiality before, during, and after the trial	____15_____

Declaration of interests	28	Financial and other competing interests for principal investigators for the overall trial and each study site	____25_____
Access to data	29	Statement of who will have access to the final trial dataset, and disclosure of contractual agreements that limit such access for investigators	____23_____
Ancillary and post-trial care	30	Provisions, if any, for ancillary and post-trial care, and for compensation to those who suffer harm from trial participation	____n/a_____
Dissemination policy	31a	Plans for investigators and sponsor to communicate trial results to participants, healthcare professionals, the public, and other relevant groups (eg, via publication, reporting in results databases, or other data sharing arrangements), including any publication restrictions	____23_____
	31b	Authorship eligibility guidelines and any intended use of professional writers	____25_____
	31c	Plans, if any, for granting public access to the full protocol, participant-level dataset, and statistical code	____23_____
Appendices			
Informed consent materials	32	Model consent form and other related documentation given to participants and authorised surrogates	__Supplementary __materials
Biological specimens	33	Plans for collection, laboratory evaluation, and storage of biological specimens for genetic or molecular analysis in the current trial and for future use in ancillary studies, if applicable	____n/a_____

*It is strongly recommended that this checklist be read in conjunction with the SPIRIT 2013 Explanation & Elaboration for important clarification on the items. Amendments to the protocol should be tracked and dated. The SPIRIT checklist is copyrighted by the SPIRIT Group under the Creative Commons "Attribution-NonCommercial-NoDerivs 3.0 Unported" license.